

# Exhibit K

Peggy Pence, Ph.D.

Page 1

IN THE UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC  
REPAIR SYSTEM PRODUCTS  
LIABILITY LITIGATION

MDL NO. 2327  
HON. JOSEPH R. GOODWIN  
U.S. DISTRICT JUDGE

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THIS DOCUMENT RELATED TO THE  
FOLLOWING CASES IN WAVE 1 OF  
MDL 200:

Donna Amsden v. Ethicon, Inc.  
Civil Action No. 2:12-cv-00960

Marie Banks v. Ethicon, Inc.  
Civil Action No. 2:12-cv-01318

Harriet Beach v. Ethicon, Inc.  
Civil Action No. 2:12-cv-00476

Sharon Boggs, et al. v.  
Ethicon, Inc., et al.  
Civil Action No. 2:12-cv-00368

DEPOSITION OF  
PEGGY PENCE, PH.D.  
MARCH 9, 2016

Karen Bollinger v. Ethicon,  
Inc.  
Civil Action No. 2:12-cv-01215

Robin Bridges v. Ethicon,  
Inc., et al.  
Civil Action No. 2:12-cv-00651

Denise Burkhart v. Ethicon,  
Inc., et al.  
Civil Action No. 2:12-cv-01023

Myra Byrd, et al., v. Ethicon,  
Inc., et al.  
Civil Action No. 2:12-cv-00748

Sharon Carpenter, et al. v.  
Ethicon, Inc., et al.  
Civil Action No. 2:12-cv-00554

## Peggy Pence, Ph.D.

Page 2	Page 4
<p>1 Carey Beth Cole, et al. v. Ethicon, Inc., et al. 2 Civil Action No. 2:12-cv-00483 3 Angela Coleman, et al. v. Ethicon, Inc., et al. 4 Civil Action No. 2:12-cv-01267 5 Fran Denise Collins v. Ethicon, Inc., et al. 6 Civil Action No. 2:12-cv-00931 7 Mary F. Cone v. Ethicon, Inc. Civil Action No. 2:12-cv-00261 8 Patricia Conti v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-00516 10 Amanda Deleon et al. v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-00358 12 Dina Destefano-Raston, et al. v. Ethicon, Inc. Civil Action No. 2:12-cv-01299 14 Karyn E. Drake, et al. v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-00747 16 Paula Fisk v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-00848 18 Karen Forester, et al. v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-00486 20 Sherry Fox, et al. v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-00878 22 Pamela Free v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-00423 24 Shirley Freeman, et al. v. Ethicon, Inc., et al.</p>	<p>1 Wilma Johnson v. Ethicon, Inc., et al. 2 Civil Action No. 2:12-cv-00809 3 Holly Jones, et al. v. Ethicon, Inc., et al. 4 Civil Action No. 2:12-cv-00443 5 Barbara Kaiser v. Ethicon, Inc., et al. 6 Civil Action No. 2:12-cv-00887 7 Margaret Kirkpatrick v. Ethicon, Inc., et al. 8 Civil Action No. 2:12-cv-00746 9 Paula Kriz, et al. v. Ethicon, Inc., et al. 10 Civil Action No. 2:12-cv-00938 11 Alfreda Lee, et al. v. Ethicon, Inc., et al. 12 Civil Action No. 2:12-cv-01013 13 JoAnn Lehman v. Ethicon, Inc., et al. 14 Civil Action No. 2:12-cv-00517 15 Heather Long v. Ethicon, Inc., et al. 16 Civil Action No. 2:12-cv-01275 17 Donna Loustaunau, et al. v. Ethicon, Inc., et al. 18 Civil Action No. 2:12-cv-00666 19 Deborah Lozano, et al. v. Ethicon, Inc., et al. 20 Civil Action No. 2:12-cv-00347 21 Dee McBrayer, et al. v. Ethicon, Inc., et al. 22 Civil Action No. 2:12-cv-00779 23 Charlene Miracle v. Ethicon, Inc., et al. 24 Civil Action No. 2:12-cv-00510 25</p>
Page 3	Page 5
<p>1 Betty Funderburke v. Ethicon, Inc., et al. 2 Civil Action No. 2:12-cv-00957 3 Teresa Georgilakis, et al. v. Ethicon, Inc., et al. 4 Civil Action No. 2:12-cv-00829 5 Rose Gomez, et al. v. Ethicon, Inc., et al. 6 Civil Action No. 2:12-cv-00344 7 Louise Grabowski v. Ethicon, Inc., et al. 8 Civil Action No. 2:12-cv-00683 9 Pamela Gray-Wheeler v. Ethicon, Inc., et al. 10 Civil Action No. 2:12-cv-00455 11 Susan Guinn v. Ethicon, Inc., et al. 12 Civil Action No. 2:12-cv-01121 13 Dawna Hankins v. Ethicon, Inc., et al. 14 Civil Action No. 2:12-cv-00369 15 Donna Hankins, et al. v. Ethicon, Inc., et al. 16 Civil Action No. 2:12-cv-01011 17 Mary Hendrix, et al. v. Ethicon, Inc., et al. 18 Civil Action No. 2:12-cv-00595 19 Rocio Herrera-Nevarez v. Ethicon, Inc., et al. 20 Civil Action No. 2:12-cv-01294 21 Barbara Hill, et al. v. Ethicon, Inc., et al. 22 Civil Action No. 2:12-cv-00806 23 Nancy Hooper, et al. v. Ethicon, Inc., et al. 24 Civil Action No. 2:12-cv-00493 25</p>	<p>1 Cynthia Nix v. Ethicon, Inc., et al. 2 Civil Action No. 2:12-cv-01278 3 Mary Jane Olson, et al. v. Ethicon, Inc., et al. 4 Civil Action No. 2:12-cv-00470 5 Noemi Padilla v. Ethicon, Inc., et al. 6 Civil Action No. 2:12-cv-00567 7 Miranda Patterson v. Ethicon, Inc., et al. 8 Civil Action No. 2:12-cv-00481 9 Jennifer Reyes, et al. v. Ethicon, Inc., et al. 10 Civil Action No. 2:12-cv-05664 11 Penny Rhynehart v. Ethicon, Inc., et al. 12 Civil Action No. 2:12-cv-01119 13 Ana Ruebel v. Ethicon, Inc., et al. 14 Civil Action No. 2:12-cv-00663 15 Patricia Ruiz v. Ethicon, Inc., et al. 16 Civil Action No. 2:12-cv-01021 17 Stacy Shultis, et al. v. Ethicon, Inc., et al. 18 Civil Action No. 2:12-cv-00654 19 Jennifer Sikes, et al. v. Ethicon, Inc., et al. 20 Civil Action No. 2:12-cv-00501 21 Carrie Smith v. Ethicon, Inc., et al. 22 Civil Action No. 2:12-cv-00258 23 Janet Smith, et al. v. Ethicon, Inc., et al. 24 Civil Action No. 2:12-cv-00861 25</p>

2 (Pages 2 to 5)

## Peggy Pence, Ph.D.

Page 6	Page 8
<p>1 Cherise Springer, et al. v. Ethicon, Inc., et al. 2 Civil Action No. 2:12-cv-00997 3 Isabel Swint, et al v. Ethicon, Inc., et al. 4 Civil Action No. 2:12-cv-00786 5 Krystal Teasley v. Ethicon, Inc., et al. 6 Civil Action No. 2:12-cv-00500 7 Susan Thaman v. Ethicon, Inc., et al. 8 Civil Action No. 2:12-cv-00279 9 Kimberly Thomas v. Ethicon, Inc., et al. 10 Civil Action No. 2:12-cv-00499 11 Mary Thurston v. Ethicon, Inc. Civil Action No. 2:12-cv-00505 12 Patricia Tyler v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-00469 14 Cathy Warlick v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-0276 16 Nancy Williams v. Ethicon, Inc. Civil Action No. 2:12-cv-00511 18 Christine Wiltgen, et al. v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-01216 20 Sandra Wolfe v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-0335 22 Rebecca Pratt v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-01273 24 25</p>	<p>1 INDEX 2 WITNESS: PEGGY PENCE, PH.D. 3 EXAMINATION PAGE 4 Ms. Sutherland 10 5 Mr. Kuntz 96 6 7 8 9 EXHIBITS 10 NUMBER PAGE 11 Exhibit 1 Notice to Take Deposition of Peggy 14 Pence 12 Exhibit 2 Rule 26 Expert Report of Dr. Peggy 20 Pence 13 Exhibit 3 Supplemental Expert Report of Peggy 21 Pence, Ph.D., Regarding Ethicon 15 Women's Health and Urology 16 Exhibit 4 Supplemental Report of Peggy Pence, 51 Ph.D., Regarding Tension Free Vaginal Tape 18 Exhibit 5 Binder titled "Prosima Systems" 16 with February 1, 2016, expert report and March 2016 supplemental report of Peggy Pence 20 Exhibit 6 Binder of supporting documentation 17 for expert report and supplemental report of Peggy Pence 22 Exhibit 7 Binder containing FDA documents 18 23 Exhibit 8 Binder containing white labeling 18 GHTF final guidance documents 24 25</p>
Page 7	Page 9
<p>1 2 Deposition of PEGGY PENCE, PH.D., taken 3 on behalf of the Defendants, before Kristi Johnson, 4 CSR No. 12585, commencing on Wednesday, March 9, 2016, 5 at 9:12 a.m., at 100 Bayview Circle, Suite 5600, Newport 6 Beach, California, pursuant to Notice of Taking Deposition. 7 8 9 APPEARANCES OF COUNSEL: 10 11 For the Plaintiff: 12 WAGSTAFF &amp; CARTMELL BY: JEFFREY KUNTZ, ESQ. 13 4740 Grand Avenue Suite 300 14 Kansas City, Missouri 64112 816.701.1124 15 JKuntz@wcllp.com 16 For the Defendant: 17 BUTLER SNOW LLP BY: KARI SUTHERLAND, ESQ. 18 1020 Highland Colony Parkway Suite 1400 19 Ridgeland, Mississippi 39158-6010 601.985.4523 20 Kari.Sutherland@butlersnow.com 21 22 23 24 25</p>	<p>1 INDEX (Continued) 2 3 EXHIBITS 4 NUMBER PAGE 5 Exhibit 9 Memorandum of Opinion and Order of 27 Judge Goodwin in Mathison vs. Boston Scientific Corporation 6 Exhibit 10 Global Harmonization Task Force, 70 Essential Principles of Safety and Performance of Medical Devices 8 Exhibit 11 Global Harmonization Task Force, 72 Clinical Evaluation 10 Exhibit 12 Global Harmonization Task Force, 86 11 Label and Instructions for Use for Medical Devices 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p>

3 (Pages 6 to 9)

## Peggy Pence, Ph.D.

Page 10	Page 12
<p>1        NEWPORT BEACH, CALIFORNIA; WEDNESDAY, MARCH 9, 2015</p> <p>2                    9:12 A.M.</p> <p>3                    ---</p> <p>4        PEGGY PENCE, PH.D.,</p> <p>5        called as a witness, having been first duly sworn, was</p> <p>6        examined and testified as follows:</p> <p>7                    ---</p> <p>8                    EXAMINATION</p> <p>9        BY MS. SUTHERLAND:</p> <p>10      Q. Good morning.</p> <p>11      A. Good morning.</p> <p>12      Q. Would you please tell me your full name?</p> <p>13      A. Peggy Jo Clark Pence.</p> <p>14      Q. Dr. Pence, what is your address?</p> <p>15      A. 1533 Miramar Drive, Newport Beach, California</p> <p>16      92661.</p> <p>17      Q. Is that your business address?</p> <p>18      A. It is my home address as well as I have an</p> <p>19      office there as well, and then I have a satellite office</p> <p>20      in Newbury Park.</p> <p>21      Q. You used to live where before?</p> <p>22      A. Newbury Park.</p> <p>23      Q. So you still have that. Is that where your</p> <p>24      employees are?</p> <p>25      A. We all work remotely. It's an address for a</p>	<p>1        will be my sixth year to teach this specific course.</p> <p>2        Q. Did you teach on GHTF last year?</p> <p>3        A. Yes.</p> <p>4        Q. The year before that?</p> <p>5        A. I don't recall without checking back on my</p> <p>6        notes and PowerPoint slides because I update them every</p> <p>7        year. Let me say I suspect, to the best of my</p> <p>8        recollection, that I did because I have always also</p> <p>9        taught an international conference on harmonization,</p> <p>10       which is relevant to drugs, and the GHTF is analogous to</p> <p>11       the international conference on harmonization but for</p> <p>12       medical devices, GHTF for medical devices. And I teach</p> <p>13       about both medical devices and drugs. So I suspect I</p> <p>14       have been doing it for several years. I just would have</p> <p>15       to -- to the extent to which I have been talking about</p> <p>16       it, because there's a lot to cover, and essentially, I</p> <p>17       have 12 weeks to cover a tremendous amount of material.</p> <p>18       So the extent to which I addressed it, I don't recall</p> <p>19       specifically as I sit here today without checking back</p> <p>20       thinking back to two years ago.</p> <p>21      Q. I'm sorry, the last part of that was?</p> <p>22      A. You had asked me about two years ago did I</p> <p>23      teach it.</p> <p>24      Q. So the answer was you think you have taught it</p> <p>25      longer than two years ago?</p>
Page 11	Page 13
<p>1        satellite office, but we're all working remotely from our</p> <p>2        homes at this point in time.</p> <p>3        Q. Are you still teaching?</p> <p>4        A. Yes.</p> <p>5        Q. Are you currently teaching or about to start?</p> <p>6        A. My class starts April 5th.</p> <p>7        Q. How long will that be?</p> <p>8        A. It goes through the end of June.</p> <p>9        Q. And remind me what you teach?</p> <p>10       A. Clinical trials and quality assurance. Biology</p> <p>11       516, if I recall correctly, is the number. It's a</p> <p>12       graduate-level course for students that are working on</p> <p>13       their master's in biotechnology at California State</p> <p>14       University, and I teach that course at the Channel</p> <p>15       Islands campus.</p> <p>16       Q. As part of the class you teach, I would assume</p> <p>17       you include teaching on FDA regulations?</p> <p>18       A. Yes, I do.</p> <p>19       Q. Do you also include teaching on Global</p> <p>20       Harmonization Task Force guidances?</p> <p>21       A. Yes, I do.</p> <p>22       Q. How long have you been including the GHTF</p> <p>23       guidances as part of your course material?</p> <p>24       A. Without checking back on my PowerPoint slides,</p> <p>25       I can't tell you exactly when I began doing that. This</p>	<p>1        A. This is my sixth year to teach this particular</p> <p>2        class.</p> <p>3        Q. You think you have taught on GHTF longer than</p> <p>4        the last two years, but you would have to check to be</p> <p>5        sure. Would that be fair?</p> <p>6        A. Yes.</p> <p>7        Q. On your GHTF course material, do you use</p> <p>8        specific guidances?</p> <p>9        A. I give them guidances to review as part of -- I</p> <p>10       present certain information in class, and then for</p> <p>11       various reading material to support what I present to</p> <p>12       them in class, I give them various guidances, whether</p> <p>13       it's drug or medical device related, and that would</p> <p>14       include GHTF guidances. And, for example, they always</p> <p>15       have an individual -- at least one, if not more,</p> <p>16       individual project assignment that they have to research</p> <p>17       and present prior to the end of class, and some of those</p> <p>18       are drug related, some of those are medical device</p> <p>19       related. I give them as resource materials the guidances</p> <p>20       and instruct them on their own as well to review those</p> <p>21       guidances and incorporate those into their thinking and</p> <p>22       their conclusions, their analyses of the problems that I</p> <p>23       give them to report on.</p> <p>24       Q. Now, do you typically, if you can recall,</p> <p>25       utilize specific GHTF guidances? In other words, could</p>

## Peggy Pence, Ph.D.

Page 14	Page 16
<p>1 you name them for me, the ones you use in class?</p> <p>2 A. I'd have to check back to tell you specifically 3 the ones that I use in class, but more than likely, they 4 would be the essential principles of safety and 5 performance. They would have to do with the clinical 6 evaluation, labeling guidances, conformity assessment 7 guidances. Also, I usually have a guest speaking that 8 comes in and talks about quality management systems, so 9 it would include the guidances on quality management 10 systems that they would have as well, clinical 11 investigations.</p> <p>12 Q. Do you have a syllabus that you have already 13 put together for the upcoming class that you're going to 14 teach in April?</p> <p>15 A. Not yet. Been too busy.</p> <p>16 Q. Do you need to get working on that?</p> <p>17 A. Yes. I'm waiting on the contract, and then it 18 will happen in the next couple of weeks.</p> <p>19 MS. SUTHERLAND: I'm going to hand you what I 20 marked as Depo Number 1 and that's your notice.</p> <p>21 (Defendant's Exhibit 1 was marked for 22 identification by the court reporter.)</p> <p>23 BY MS. SUTHERLAND:</p> <p>24 Q. Did you bring some documents with you today?</p> <p>25 A. I did.</p>	<p>1 and have them printed, but it's probably --</p> <p>2 MR. KUNTZ: Whatever you want to do. I think 3 the last depo we turned them around pretty quick.</p> <p>4 THE WITNESS: It took them a while to get them 5 back to me. I think there was confusion about my 6 address. If we can just get them back quickly.</p> <p>7 BY MS. SUTHERLAND:</p> <p>8 Q. While we're here, give me again the street 9 address where you want them shipped back?</p> <p>10 A. 1533 Miramar Drive, Newport Beach, California 11 92661.</p> <p>12 Q. Would you mind if I put stickers on them, or 13 would you like me to tape them, for marking the binders 14 as exhibits?</p> <p>15 A. Whatever you want to do.</p> <p>16 MS. SUTHERLAND: I'll stick a sticker on the 17 outside, and I'm sure you can scrape it off later.</p> <p>18 I'll mark as Exhibit Number 5 your white binder 19 called "Prosima Systems" that is listing your February 20 expert report and your March supplemental report, and it 21 appears there are three tabs in it and a number of 22 colored tabs, five tabs, and supplements.</p> <p>23 (Defendant's Exhibit 5 was marked for 24 identification by the court reporter.)</p> <p>25 THE WITNESS: That's the supplement and the</p>
Page 15	Page 17
<p>1 Q. Can I take a peek at what you brought? Just 2 this binder?</p> <p>3 A. No. I have others, too, in case you need them. 4 You were asking about GHTF documents. Those 5 are ones that have been referenced in my report. I also 6 brought FDA proposed orders and the reclassification of 7 transvaginal mesh for pelvic organ prolapse repair. This 8 is the document, the compilation of the documents that 9 are footnoted in my Prosima report.</p> <p>10 Q. Ethicon documents?</p> <p>11 A. Ethicon or other documents that are referenced, 12 publications that are referenced in footnotes in the body 13 of my main report.</p> <p>14 Q. Now, if I want to get copies of your binders, 15 do you remember how we have done that before?</p> <p>16 A. We have done it two ways. Last time they were 17 taken and returned to me, but it took a while to get them 18 back, so I'm not sure why it took so long. I will need 19 them for reference. If they were to be taken, could they 20 be returned quickly? That's how we did it the last time.</p> <p>21 Q. If we could -- we'll work with Golkow to make 22 sure we have a quick turnaround. Would that be okay with 23 you if Kristi took them and then we made an effort to be 24 sure we got them back to you?</p> <p>25 A. Yes. We can either do that or I can take them</p>	<p>1 exhibits to the supplement.</p> <p>2 BY MS. SUTHERLAND:</p> <p>3 Q. That will be Number 5, and I will hand that 4 back to you.</p> <p>5 Number 6 I will mark -- I knew this looked 6 familiar with Cavness marked out and MDL marked on there.</p> <p>7 A. My staff knows that Cavness was Prosima. 8 Everything that's Prosima, they write Cavness on it.</p> <p>9 MS. SUTHERLAND: So I will mark as Exhibit 10 Number 6 your orange binder that has tabs in yellow with 11 numbers delineated on the side which would reflect 12 footnote numbers?</p> <p>13 THE WITNESS: Yes.</p> <p>14 MS. SUTHERLAND: And if we could, when we get 15 those copies made, we'll have the tabs the same that 16 delineate the numbers.</p> <p>17 (Defendant's Exhibit 6 was marked for 18 identification by the court reporter.)</p> <p>19 BY MS. SUTHERLAND:</p> <p>20 Q. There are orange tabs. Those just separate the 21 actual documents?</p> <p>22 A. The pages of the report. The pages of the 23 report -- the way Christine put that together was the 24 pages of the report, and then behind the pages of the report is the documents that are referenced in the</p>

## Peggy Pence, Ph.D.

Page 18	Page 20
<p>1 footnotes for that page.</p> <p>2 Q. Very coordinated. I see what you're saying.</p> <p>3 I'll hand that back to you.</p> <p>4 The next binder that I will mark as Number 7,</p> <p>5 which is just a blue binder that's not labeled and has an</p> <p>6 article in the front flap as well as articles in the</p> <p>7 binder.</p> <p>8 (Defendant's Exhibit 7 was marked for</p> <p>9 identification by the court reporter.)</p> <p>10 BY MS. SUTHERLAND:</p> <p>11 Q. This just looks to be primarily FDA documents?</p> <p>12 A. Yes.</p> <p>13 MS. SUTHERLAND: Then Exhibit 8 is a blue</p> <p>14 binder with white labeling GHTF final guidance documents.</p> <p>15 (Defendant's Exhibit 8 was marked for</p> <p>16 identification by the court reporter.)</p> <p>17 BY MS. SUTHERLAND:</p> <p>18 Q. And am I to understand these are the GHTF</p> <p>19 guidance documents in your Prosima report?</p> <p>20 A. Yes, there are initial ones in there as well</p> <p>21 that are not necessarily footnoted in my report.</p> <p>22 Q. Do you know which ones that are additional that</p> <p>23 are not in your report?</p> <p>24 A. I could go through and probably tell you.</p> <p>25 Q. If you can do that quickly, I'd appreciate it</p>	<p>1 Q. What footnote is that?</p> <p>2 A. That is in Exhibit 1. It is Footnote 41 on</p> <p>3 page 8. Let me see if there are any others. On page 11</p> <p>4 of my Exhibit 1, I did not include copies in the binder</p> <p>5 of the GHTF roles and responsibilities, guiding</p> <p>6 principles, and operating procedures. I did not include</p> <p>7 copies of those guidances.</p> <p>8 Q. My original question was were there guidances</p> <p>9 in the binder that you saw that were not listed in your</p> <p>10 report?</p> <p>11 A. Yes.</p> <p>12 Q. Just remind me again, what were those?</p> <p>13 A. The clinical evidence I don't believe is</p> <p>14 referenced and the "Review of Current Requirements on</p> <p>15 Postmarket Surveillance," from a quick review, doesn't</p> <p>16 appear to be included.</p> <p>17 MS. SUTHERLAND: I'm going to hand you what I</p> <p>18 have marked as deposition Exhibit Number 2.</p> <p>19 (Defendant's Exhibit 2 was marked for</p> <p>20 identification by the court reporter.)</p> <p>21 BY MS. SUTHERLAND:</p> <p>22 Q. If you would, identify that for me.</p> <p>23 A. This appears to be my expert report of</p> <p>24 February 1st, 2016, on Prosima.</p> <p>25 Q. That has five exhibits to it?</p>
Page 19	Page 21
<p>1 just so I know.</p> <p>2 A. Sure. To the best of my recollection as I sit</p> <p>3 here today.</p> <p>4 Q. I understand. I understand.</p> <p>5 A. The clinical evidence, I would have to double</p> <p>6 check, but the "Postmarket Clinical Follow-Up Studies," I</p> <p>7 would need to check on that. I believe the "Review of</p> <p>8 Current Requirements on Postmarket Surveillance."</p> <p>9 Q. You are listing for me the ones that are not</p> <p>10 listed in your report; is that right?</p> <p>11 A. To the best of my recollection without cross</p> <p>12 referencing my report. I can go through them</p> <p>13 individually and check them pretty quickly.</p> <p>14 Q. I'm running through your footnotes as well just</p> <p>15 to double check the ones you have called out.</p> <p>16 A. They would be predominantly referenced in the</p> <p>17 Exhibit 1. They might be in other places as well, but</p> <p>18 specifically, in Exhibit 1.</p> <p>19 I do note that it looks like I did not include</p> <p>20 in here the "Implementation of Risk Management</p> <p>21 Principles." It doesn't look like I brought a copy of</p> <p>22 that one in the binder.</p> <p>23 I'm sorry, I do have "Postmarket Clinical</p> <p>24 Follow-Up Studies." It is referenced in my Exhibit 1 to</p> <p>25 my supplemental report.</p>	<p>1 A. Yes. Shall I check to make sure they are all</p> <p>2 here?</p> <p>3 Q. I think they are. It never hurts to check. I</p> <p>4 think they're separately stapled so you can tell easily.</p> <p>5 A. Yes, there are five exhibits.</p> <p>6 MS. SUTHERLAND: I am going to hand you what I</p> <p>7 have marked as deposition Exhibit Number 3.</p> <p>8 (Defendant's Exhibit 3 was marked for</p> <p>9 identification by the court reporter.)</p> <p>10 BY MS. SUTHERLAND:</p> <p>11 Q. Now, that is what was provided to us in March</p> <p>12 as your supplemental report on Prosima and Prolift; is</p> <p>13 that correct?</p> <p>14 A. That is correct. I'm just checking to make</p> <p>15 sure both exhibits are attached. Yes, they are.</p> <p>16 Q. What was the date of that report, Dr. Pence?</p> <p>17 A. March 3rd, 2016.</p> <p>18 MS. SUTHERLAND: I may ask you some questions</p> <p>19 about that. I'll just put this caveat that I'm not going</p> <p>20 to waive my objections to the late filing of that after</p> <p>21 the plaintiff's expert deadline, be that as it may for</p> <p>22 whatever good that does.</p> <p>23 MR. KUNTZ: I'll have to --</p> <p>24 MS. SUTHERLAND: Say you would object?</p> <p>25 MR. KUNTZ: -- pipe in. I think the rules</p>

## Peggy Pence, Ph.D.

Page 22	Page 24
<p>1 allows -- frankly, I think it just organized it and      2 tailored it to what we were going to talk about were      3 issues. I don't think there's any new opinions. It is      4 what it is, I agree.</p> <p>5 BY MS. SUTHERLAND:</p> <p>6 Q. Is there anything in your supplemental report      7 that you're relying on that was not available to you      8 before February 1, 2016?</p> <p>9 A. I had not had an opportunity to review      10 Dr. Weisberg's late 2015 testimony with regard to the      11 label changes for Gynemesh PS.</p> <p>12 Q. Do you know when he was deposed?</p> <p>13 A. If I recall, it was in November.</p> <p>14 Q. Twelve and thirteen?</p> <p>15 A. Yes, of 2015.</p> <p>16 Q. Do you know if the transcript was available for      17 that prior to February 1, 2016?</p> <p>18 A. I anticipate it was.</p> <p>19 Q. When did you get a copy of it?</p> <p>20 A. I don't recall the exact date.</p> <p>21 Q. Did you get a copy of it in March?</p> <p>22 A. No, I did get it prior to that.</p> <p>23 Q. Did you get a copy of it before your      24 February 2016 Prosima report?</p> <p>25 A. I don't recall specifically as I sit here</p>	<p>1 Q. I understand that. To get an answer to my      2 question, other than Dr. Weisberg's deposition and the      3 exhibits attached to his deposition, are there other      4 materials that were not available to you prior to      5 February 1, 2016, that you cite in your supplemental      6 report?</p> <p>7 A. No.</p> <p>8 Q. Now, in your supplemental report, as I      9 understand it, that applies to, obviously, the Prosima      10 report from February of 2016?</p> <p>11 A. Yes.</p> <p>12 Q. And then you reference four Prolift reports;      13 correct?</p> <p>14 A. Yes.</p> <p>15 Q. Now, as far as any Ethicon mesh devices to      16 treat prolapse, are those the reports we're talking      17 about?</p> <p>18 A. Yes.</p> <p>19 Q. So four for Prolift, one for Prosima, and then      20 the supplement?</p> <p>21 A. Yes, and two of the Prolift were supplemental      22 reports.</p> <p>23 Q. Now, when did you draft your supplemental      24 report?</p> <p>25 A. The March 3rd, 2016, one?</p>
Page 23	Page 25
<p>1 today.</p> <p>2 MR. KUNTZ: I'll have to make a record because      3 I have to. I don't think that that -- my position is      4 that it's just reliance materials that further support      5 her opinions that she's been given for four or five years      6 in this litigation. It's not a new opinion. In fact,      7 Ethicon changed the IFU to list things she's been saying      8 for three or four years that should have been in the IFU.      9 I don't think it's a new opinion. I think it's      10 supplemental materials that support her opinion, and the      11 rules allow you to file supplemental reliance list      12 30 days before trial.</p> <p>13 BY MS. SUTHERLAND:</p> <p>14 Q. Other than Dr. Weisberg's deposition      15 transcript, were there any other materials that weren't      16 available to you before February 1, 2016, in your      17 supplemental report?</p> <p>18 A. Of course, along with his -- Dr. Weisberg that      19 is -- deposition, the exhibits that were attached to      20 that, of course, but as I stated in my supplemental      21 report, there are no new opinions. I didn't change any      22 opinions. I just provided supplemental to my prior      23 reports, I should say, information that I thought was      24 additionally supportive to my opinions, my prior      25 opinions.</p>	<p>1 Q. Yes, ma'am.</p> <p>2 A. It would have been late February to early      3 March.</p> <p>4 Q. Why did you draft it?</p> <p>5 A. Because I felt after when I reviewed -- when I      6 had an opportunity to review Dr. Weisberg's deposition      7 and the attachment, the exhibits, I mean to say, to that,      8 I recognized that it was additionally supportive of my      9 opinions because the modifications, the revisions to the      10 labeling as regards to risk information, included      11 information that, from my original reports dating back to      12 2012 for my first Prolift report, in fact, contained      13 information that ultimately Ethicon added after they      14 received notification from Health Canada that Health      15 Canada was requesting updates to the labeling. And I      16 thought that was substantiation of my opinions, and it      17 was important to document that. In the course of doing      18 that, I also decided to add some additional information      19 supportive of my opinions about failure to test from      20 other authoritative bodies.</p> <p>21 Q. Why did you feel like you needed to add other      22 information from other authoritative bodies in your      23 supplemental report?</p> <p>24 A. I thought it was important to -- I have added      25 it in some other reports that I have done that I hadn't</p>

7 (Pages 22 to 25)

## Peggy Pence, Ph.D.

Page 26	Page 28
<p>1 added initially, if I recall correctly as I sit here      2 today, in my first Prolift report. And I thought it      3 would be helpful and that I would add it as a result of      4 that since I was updating the report, and then, of      5 course, the GHTF information.</p> <p>6 Q. Is the GHTF information material that was not      7 included in your Prolift 2012 report?</p> <p>8 A. That's correct.</p> <p>9 Q. Was the GHTF information included in your -- I      10 think it's 2014 Prolift report?</p> <p>11 A. No.</p> <p>12 Q. So the only GHTF information that you have      13 supplied now for Prolift is your March 2016 supplemental      14 report; is that correct?</p> <p>15 A. Yes.</p> <p>16 Q. Did you review any ruling by Judge Goodwin      17 addressing the scope of your opinions before you drafted      18 your supplemental report?</p> <p>19 MR. KUNTZ: Objection. Vague as to time. What      20 opinion?</p> <p>21 BY MS. SUTHERLAND:</p> <p>22 Q. Do you understand my question?</p> <p>23 A. Yes, but if you'll repeat it, please.</p> <p>24 Q. Absolutely. Let me ask it this way: Have you      25 ever reviewed any opinion from Judge Goodwin addressing</p>	<p>1 A. You'll note that when I wrote my Prosima      2 report, which is dated February 1st, that it has an      3 exhibit, the GHTF information, and that is not the first      4 report for mesh products where I included GHTF. Back, if      5 I'm recalling correctly, in 2014, I wrote a Boston      6 Scientific report in which I included GHTF information,      7 and so when I wrote the Prosima report, I included the      8 GHTF information understanding instead of FDA regulations      9 based on my understanding of the concerns about FDA      10 sometimes being allowed, sometimes not being allowed, and      11 that there are other standards on which to rely. So when      12 I was doing the supplement, I realized that I had never      13 done that for Prolift. Prolift only has FDA information      14 and that it was appropriate and relevant to also include      15 the GHTF information for Prolift as well as Prosima.</p> <p>16 Q. Would it be fair to say that you added in the      17 GHTF information in your Prosima February 2016 report in      18 part because of Judge Goodwin's order excluding opinions      19 where you just rely on FDA regulations?</p> <p>20 A. That isn't recent. Although this Exhibit 9 is      21 dated May 2015, as I mentioned, I had previously added      22 GHTF into a prior report understanding, back a couple      23 years or more ago, that at least for the MDL litigation,      24 that the FDA was not to be a part of that litigation, and      25 there are other standards that the industry relies on</p>
Page 27	Page 29
<p>1 the scope of your opinions that he would allow at trial?</p> <p>2 A. Yes, some time ago I did.</p> <p>3 Q. Did you review an opinion from May of 2015 in a      4 Boston Scientific order addressing the scope of your      5 opinions?</p> <p>6 A. I don't recall the date of the order      7 specifically. If you have it, I can take a look at it      8 and tell you if that's what I reviewed.</p> <p>9 MS. SUTHERLAND: I'm going to hand you what I      10 am marking as number 9.</p> <p>11 (Defendant's Exhibit 9 was marked for      12 identification by the court reporter.)</p> <p>13 BY MS. SUTHERLAND:</p> <p>14 Q. Take a look at that and tell me if that's the      15 opinion by Judge Goodwin that you may recall reviewing.      16 For ease of reference, your part begins around page 9.</p> <p>17 A. I did find it, thank you. I am going through      18 it to see if it seems like what I reviewed. This appears      19 to be what I reviewed, if not very similar to what I      20 reviewed.</p> <p>21 Q. Dr. Pence, after you reviewed deposition      22 Exhibit Number 9, or if I understand your testimony      23 correctly an opinion similar to it, did you decide to add      24 in information about GHTF to your reports about Ethicon      25 mesh?</p>	<p>1 that are relevant internationally, and in particular to      2 the U.S. and that the U.S. has participated in      3 establishing those standards, so that to exclude other      4 standards was not presenting a comprehensive approach to      5 the available evidence to support my opinions.</p> <p>6 Q. If I'm understanding you correctly, I believe      7 you testified that you're not offering any new opinions      8 regarding Prolift other than what was set out in your      9 2012 and 2014 reports; correct?</p> <p>10 A. That is correct.</p> <p>11 Q. And in those 2012 and 2014 reports, what you      12 relied on to support your opinions in part were FDA      13 regulations; correct?</p> <p>14 A. Yes, as a regulatory expert working in the      15 United States.</p> <p>16 Q. That would seem to make sense, wouldn't it?</p> <p>17 A. Exactly, but there are additional standards,      18 and because I am a regulatory expert working in the U.S.,      19 I initially included FDA standards. Recognizing that for      20 certain courts that that information may not be allowed      21 to be presented, I wanted to provide a more comprehensive      22 and broader base for my opinions and reflect the      23 international standards, which include much of the same      24 types of information, but it's an international standard      25 that substantiates my opinions.</p>

## Peggy Pence, Ph.D.

Page 30	Page 32
<p>1       Q. Is it your testimony that the opinions on 2 Prolift that you offered in the 2012 and 2014 reports, 3 you're not relying on FDA regulations to support those 4 opinions?</p> <p>5       A. No, that's misrepresenting what I'm trying to 6 say.</p> <p>7       Q. Then let me follow up.</p> <p>8           Is it your testimony then that, in fact, you 9 are still relying on FDA regulations to support the 10 opinions you set out in your 2012 and 2014 Prolift 11 reports?</p> <p>12      A. The best way to answer that is that both FDA 13 regulations and the GHTF guidances support my opinions. 14 So I'm not saying that my opinions aren't supported by 15 FDA regulations. They are, but my opinions are also 16 supported by the GHTF guidance documents. The GHTF -- 17 the purpose of that was to harmonize international 18 standards.</p> <p>19      Q. I'll get to that. Let me get back on track. I 20 got off my outline.</p> <p>21       Looking back at your supplemental report, there 22 are two exhibits to that; correct?</p> <p>23      A. Yes.</p> <p>24      Q. When I say supplemental report, I know you have 25 got a TVT supplemental report I haven't marked yet. For</p>	<p>1       different than Exhibit 1 that goes to the supplemental 2 report; correct?</p> <p>3       A. It has some additions.</p> <p>4       Q. The supplemental report has some additions?</p> <p>5       A. Yes.</p> <p>6       Q. Within that month time frame, from February to 7 March, why did you add in the supplement additions?</p> <p>8       A. I felt they were helpful.</p> <p>9       Q. Can you tell me which ones you added in?</p> <p>10      A. We can do a comparison here. One thing I know 11 for sure that I added was further information on the 12 process by which the GHTF documents were developed, and 13 that is its own section, Section 4, starting on page 11 14 of Exhibit 1 to the supplemental report, titled 15 "Supplementary Information Regarding GHTF Procedures: 16 All Decisions and Actions By Consensus."</p> <p>17      Q. While we're on that, let me interrupt you for 18 just a minute.</p> <p>19           The five study groups that you list there on 20 page 11, are those the only five study groups that GHTF 21 had during the 20-year time frame that it was ongoing?</p> <p>22      A. To my understanding, that's correct, yes.</p> <p>23      Q. Now let me ask you: Do you know the makeup of 24 any of the study groups?</p> <p>25      A. Can you clarify what you mean by makeup?</p>
Page 31	Page 33
<p>1 now I'm focusing on the Prosima and Prolift one I marked. 2       There are two exhibits to that; correct?</p> <p>3       A. Yes.</p> <p>4       Q. One is an industry standards document that you 5 drafted?</p> <p>6       A. Yes.</p> <p>7       Q. Dated March 3rd, 2016?</p> <p>8       A. Yes.</p> <p>9       Q. And then there's a MAUDE report; correct?</p> <p>10      A. Yes.</p> <p>11      Q. M-A-U-D-E, all caps. Tell Kristi what that 12 stands for.</p> <p>13      A. Manufacturer and user facility device 14 experience database.</p> <p>15      Q. Now, in your Prosima original report, the 16 February 2016 report, you also have an exhibit that is 17 applicable industry standards; correct?</p> <p>18      A. I'm sorry, can you repeat that?</p> <p>19      Q. No worries.</p> <p>20       In your original Prosima report from 21 February 2016, your first exhibit is also applicable 22 industry standards?</p> <p>23      A. Yes.</p> <p>24      Q. Now, Exhibit 1, which is applicable industry 25 standards for the February Prosima report, is somewhat</p>	<p>1       Q. Sure.</p> <p>2       As I understand it, GHTF included, obviously, 3 regulatory agencies?</p> <p>4       A. Right.</p> <p>5       Q. Did it include industry representatives?</p> <p>6       A. Yes.</p> <p>7       Q. Were consumer representatives included?</p> <p>8       A. It was a mix of regulatory and -- it was a 9 partnership, if you will, between regulatory and 10 industry. For example, AdvaMed represented -- was 11 represented in the various GHTF groups.</p> <p>12      Q. Which ones?</p> <p>13      A. I can't tell you specifically as I sit here 14 today.</p> <p>15      Q. During the whole time frame or specific times?</p> <p>16      A. I don't have the information available to tell 17 you specifically. I do know they participated, other 18 industry representative groups as well participated, some 19 specific companies. The aim was to have equal 20 representation between regulators and industry groups.</p> <p>21      Q. First of all, let me ask you: How do you know 22 AdvaMed was in the study groups?</p> <p>23      A. Because I did some of my own independent 24 research and was able to confirm, to the best of my recollection. For example, AdvaMed was, I believe Boston</p>

## Peggy Pence, Ph.D.

Page 34	Page 36
<p>1 Scientific was, to the best of my recollection, I believe      2 Medtronic was, some of the ones I was able to find, best      3 of my recollection, as I sit here today.      4 Q. How did you find them?      5 A. By Internet searching and trying to find      6 information on the identity of who was in particular      7 groups.      8 Q. Just trolling through the Internet,      9 essentially, to find out?      10 A. Doing specifically directed searches looking to      11 see what I could find to support that information.      12 Q. Now, in your searches, was Ethicon ever a      13 member of any of the five study groups at GHTF?      14 A. I don't recall seeing Ethicon specifically, as      15 I sit here today.      16 Q. What about J&amp;J?      17 A. A lot of that information just isn't available      18 online. I can't say if they were or were not, but they      19 were certainly represented by AdvaMed.      20 Q. Were they a member of AdvaMed at the time      21 AdvaMed was a member of GHTF?      22 A. I don't have that specific information as I sit      23 here today, but certainly, AdvaMed, the working group      24 that put together a presentation for the 2011 advisory      25 meeting, Ethicon participated in that and that was</p>	<p>1 sit here today.      2 Q. The years that AdvaMed, from what you saw,      3 worked with GHTF, do you know those years?      4 A. I don't recall those specifically as I sit here      5 today.      6 Q. Now, if I asked you the same questions with      7 respect to Johnson &amp; Johnson, do you know whether or not      8 Johnson &amp; Johnson was ever a member of GHTF?      9 A. I don't know as I sit here today. I don't have      10 a list of all of the membership.      11 Q. You did say Boston Scientific; right?      12 A. Yes.      13 Q. Do you know when Boston Scientific was a member      14 of GHTF?      15 A. I don't recall the date as I sit here today.      16 Q. Do you know which study group they might have      17 been in?      18 A. I don't recall as I sit here today.      19 Q. I was curious on that one.      20 What about any other pelvic mesh manufacturer?      21 A. As I said earlier, the information on specific      22 memberships and the different study groups, although I      23 did look for it, I was unable to find a great deal of      24 information about that, except to know as it's set out      25 that in the membership of GHTF, that it is an equal -- it</p>
Page 35	Page 37
<p>1 through AdvaMed.      2 Q. That was for FDA, though; right?      3 A. Yes.      4 Q. But we're talking about GHTF.      5 A. Yes, I understand that, but they were certainly      6 working through AdvaMed at that time.      7 Q. So let me close the loop on that.      8 Do you have information showing that in 2011,      9 at the same time that Ethicon was in AdvaMed working for      10 the FDA group in 2011, that they were also working in one      11 of the study groups in GHTF?      12 Was that a convoluted question? I can ask that      13 better.      14 A. Yes.      15 Q. Your pretext or your preface is that Ethicon      16 was working with AdvaMed in 2011 during the whole time      17 frame with the panel meeting and FDA in 2011?      18 A. Yes.      19 Q. Now, as I understood your testimony, you      20 initially said that you knew that Ethicon was in AdvaMed      21 and that AdvaMed was working with GHTF?      22 A. I knew that they were a member of AdvaMed.      23 Based on the information that I have, it appears that      24 they're a member of AdvaMed. The years of their      25 membership, I don't have that information available as I</p>	<p>1 was, as you know, disbanded and transferred to IMDRF,      2 which is all regulators. But during its 20-year history,      3 the aim was to be an equal partnership between industry      4 and the regulators internationally with the five founding      5 members, and then there's some additional groups that      6 joined as well in 2006.      7 Q. Why did it disband, GHTF, do you know?      8 A. I don't have specific reason to offer as to why      9 they disbanded. They did transfer their work over to      10 IMDRF, and it's made up of voluntary membership of      11 regulators, IMDRF.      12 Q. Is FDA a member of IMDRF?      13 A. Yes. To my understanding, that's correct.      14 Q. When did GHTF disband?      15 A. 2012.      16 Q. Did IMDRF, to your knowledge, ever make some      17 sort of statement adopting the GHTF guidances?      18 A. Yes. If you go on the IMDRF website, you will      19 see that they have GHTF archives, and then they have a      20 section where you can have IMDRF documents and GHTF      21 documents. And the GHTF documents and all of those that      22 are included in the binder that we marked as Exhibit 8      23 are considered current based on that website. If you go      24 on the IMDRF website, you will see archived documents      25 which they will tell you are no longer considered</p>

## Peggy Pence, Ph.D.

Page 38	Page 40
<p>1 current. They are there for reference. They have a list      2 of GHTF documents which are considered current posted on      3 their website.</p> <p>4 Q. And the ones that are in your binder and that      5 you have relied on in your reports, are they all under      6 the current part of the IMDRF website?</p> <p>7 A. Yes. I went through and verified that each one      8 is listed still on what's considered current by IMDRF.</p> <p>9 Q. Now let me ask you about Exhibit 2 of your      10 supplemental report. That is the MAUDE MDR reports. Let      11 me tell you what I think this is and you tell me if I'm      12 right.</p> <p>13 As far as I understand it, what you have got      14 listed here in the three different charts are reports      15 that were reported to FDA that you located on the MAUDE      16 database that, in some extent, reference pelvic mesh?</p> <p>17 A. Yes. For these particular products and      18 manufacturers, yes.</p> <p>19 Q. Did you do the search?</p> <p>20 A. It was done under my direction by Christine      21 Swanson, who is one of my staff.</p> <p>22 Q. What search terms did she use to come up with      23 the numbers to populate the different columns?</p> <p>24 A. I would have to -- I would have to present that      25 to you as a list. For example --</p>	<p>1 should say.      2 Q. I'm trying to follow you there.      3 Does she not have a college degree?      4 A. I don't believe she does, not a bachelor's.      5 Q. She did graduate from high school, though;      6 right?      7 A. Yes.      8 Q. How old is she?      9 A. I don't know specifically. We're not allowed      10 to ask those questions as an employer.      11 Q. She's not a teenager, is she?      12 A. No. She has a son that's a teenager.      13 Q. Did you look at any of the actual reports      14 themselves from the MAUDE database?      15 A. Yes.      16 Q. Did you look at all of them?      17 A. I have not looked at every one, no.      18 Q. Can you tell me, on the Ethicon sling column,      19 the combined products, there's a total there of 23,083      20 MDRs, can you tell me how many reports out of those      21 23,000 plus you actually looked at?      22 A. I can't give you a specific number, no.      23 Q. Did you look at a hundred?      24 A. I certainly looked at more than a hundred, yes.      25 Q. Of the Ethicon ones?</p>
Page 39	Page 41
<p>1 Q. Did you tell her what to search for?      2 A. Yes.      3 Q. Tell me what you told her, essentially.      4 A. I told her to search from 1999 through the end      5 of 2015 for these particular manufacturers and these      6 product names. And then for Ethicon, for example, where      7 we have combined the sling products, TVT, TVT-O, TVT      8 Obturator, TTVT Exact, TTVT Abbrevio, TTVT Secure. She      9 applied the manufacturer names, the names of the      10 products, and to extract MDR reports that had been      11 submitted to the FDA for those particular products for      12 those particular manufacturers that are listed here.      13 Q. Now, what was the name of the lady that --      14 A. Christine Swanson.      15 Q. What are her qualifications or background?      16 A. She has a great deal of background as an      17 analyst, a data analyst.      18 Q. Does she have a master's or something?      19 A. No.      20 Q. Tell me if you know her educational background.      21 A. I don't believe she actually has -- to the best      22 of my recollection as I sit here today, I don't believe      23 she has a bachelor's degree. She has, for example,      24 previously worked at Amgen as an analyst and she has      25 extensive experience in data analytics, data analysis, I</p>	<p>1 A. Yes.      2 Q. Why did you look at them?      3 A. Well, I looked at them for a variety of      4 reasons. I have reviewed issue reports in the past as      5 well, and I reviewed MDR reports to look at the      6 information in the MDR reports. First of all, when I      7 give my staff direction, I verify what they're doing and      8 that it's being done correctly. For example, if you look      9 at my Prolift report, which I don't have a copy here --      10 Q. It's burned in my brain.      11 A. If you look at my Prolift report, if I'm      12 recalling correctly as I sit here today, you will see      13 there are tabular presentations of particular adverse      14 events that are reported in the MDR database. When I      15 give my staff direction, in order to present, pull out      16 this type of a table, it's a tabulation of numbers of MDR      17 reports that come up for specific search terms. But      18 within the body of the MDR reports, there's a discussion      19 description of the adverse event or events that occurred      20 and were reported in the MDR report. For a tabulation      21 such as those that were presented in my Prolift report,      22 you have to go through and read the MDR report and      23 extract the information that shows there's an erosion or      24 if there's dyspareunia or whatever the adverse event may      be.</p>

## Peggy Pence, Ph.D.

Page 42	Page 44
<p>1       Q. Did you do that for this chart?</p> <p>2       A. This is a tabulation for all MDR reports. It's 3 not a tabulation of what the specific adverse events were 4 that were reported in those. That information, as you 5 know in the Prolift report, there is that type of 6 information and we did do that for that.</p> <p>7       Q. Unfortunately, I can't ask you about that 8 because you have been deposed in the Prolift report.</p> <p>9       For this report, Exhibit 2 to your supplement, 10 would I be correct that you don't have it broken out as 11 to what the event is that occurred for, for instance, the 12 Ethicon sling products combined?</p> <p>13      A. That's correct. This is a tabulation of the 14 total number of MDR reports for these products, these 15 manufacturers.</p> <p>16      Q. Do you have that information stored somewhere 17 else, like at Symbion?</p> <p>18      A. For some of them we do where we have gone 19 through and pulled that information out. It takes, 20 obviously, a lot of time to read through each of those 21 and to pull the information out and tabulate it, and we 22 have done that for a number of these.</p> <p>23      Q. But not for what I'm now looking at as 24 Exhibit 2?</p> <p>25      A. For some of those that information is</p>	<p>1       for instance, if someone had both a TVT and a Prolift 2 implanted and there was one MDR, do you know where she 3 would stick the MDR?</p> <p>4       A. Without checking back with her, I would 5 anticipate that it probably would have appeared in both 6 columns.</p> <p>7       Q. If I'm looking at the top chart -- and let's 8 just stick with the Ethicon sling column for now -- you 9 can see it jumps from in 2011, there were 270 reports. 10      Do you see where I am?</p> <p>11      A. Yes.</p> <p>12      Q. The next year, 2012, there were over 3,000 13 reports?</p> <p>14      A. Correct.</p> <p>15      Q. And then the next year, 2013, there were over 16 16,000 reports; right?</p> <p>17      A. Yes.</p> <p>18      Q. First of all, let me ask you, for the year 19 where the number was put, is that just the year of the 20 report, when the event was reported?</p> <p>21      A. Yes.</p> <p>22      Q. So if the event occurred, say, in 2003, but it 23 was reported in 2007, the number goes in 2007?</p> <p>24      A. For this chart, yes.</p> <p>25      Q. For this chart?</p>
Page 43	Page 45
<p>1       available. Not for all of the MDR reports that are in 2 this tabulation.</p> <p>3       Q. And the sum that you're talking about that's 4 available are set out in your previous Prolift reports?</p> <p>5       A. And other reports.</p> <p>6       Q. And TVT reports?</p> <p>7       A. And also the Boston Scientific, for example.</p> <p>8       Q. Did you make efforts to call out any duplicate 9 reports?</p> <p>10      A. We do try to do that, yes.</p> <p>11      Q. Tell me how you try to do that for this 12 exhibit, Exhibit 2.</p> <p>13      A. Well, we have done that previously. If it 14 appears --</p> <p>15      Q. I want to hear about for this one.</p> <p>16      A. If there's definitely a duplicate. For this, I 17 would have to double check exactly how we did it for this 18 particular report.</p> <p>19      Q. Do you know, as you sit here today, that 20 efforts were, in fact, taken to call out duplicates from 21 the numbers that are represented in Exhibit 2?</p> <p>22      A. To the best of my recollection as I sit here 23 today, yes. Christine always pays attention to try to 24 call out anything that's an obvious duplicate.</p> <p>25      Q. Now, did Christine make efforts to call out,</p>	<p>1       A. Yes.</p> <p>2       Q. Outside a mass litigation like we have here 3 with mesh, have you seen numbers jump to the percentage 4 that you're seeing here, for instance, from 2012 with 5 3,000 reports to 2013 with 16,000 reports? Have you seen 6 that outside of litigation?</p> <p>7       A. Well, I have not looked at it for every product 8 outside of litigation. For those products that I have 9 looked at, I have seen that happen more typically with 10 litigation or if there's some kind of a safety alert or 11 some type of a notification from the FDA that makes 12 people more aware.</p> <p>13      Q. Did you make any notations or record of how 14 many of the reports were from litigation?</p> <p>15      A. That information is available. I don't have it 16 in this document.</p> <p>17      Q. When you say it's available, it's in the MDR 18 report?</p> <p>19      A. Right.</p> <p>20      Q. Do you all have some kind of work product put 21 together where you have delineated how many of the 16,000 22 are from litigation?</p> <p>23      A. For some of the products we do. For all of the 24 totals here, no, but, for example, I don't have it for 25 AMS. I do have it for some of these products.</p>

## Peggy Pence, Ph.D.

Page 46	Page 48
<p>1       Q. Do you have it for Ethicon products?</p> <p>2       A. For some of them, yes.</p> <p>3       Q. Which ones?</p> <p>4       A. I don't remember specifically without checking</p> <p>5       back as I sit here today.</p> <p>6       Q. When you say you have it for some products, are</p> <p>7       you saying for all of the TVT reports from '99 to 2015,</p> <p>8       you may already have that information of how many of</p> <p>9       those reports were from litigation --</p> <p>10      A. Yes.</p> <p>11      Q. -- like for TVT?</p> <p>12      A. Yes. We have done that analysis for a number</p> <p>13      of the different products.</p> <p>14      Q. Up through 2015?</p> <p>15      A. Not completely through 2015 because, if I</p> <p>16      recall correctly as I sit here today, my prior reports</p> <p>17      had not gone through 2015, and for this exhibit, updated</p> <p>18      it through the end of 2015 since we're now into 2016.</p> <p>19      Q. The reason I'm asking is, I think you and I had</p> <p>20      talked before about your previous MAUDE searches, and I</p> <p>21      did not recall that you had pulled out the ones that were</p> <p>22      from litigation. That's what I'm trying to help jog your</p> <p>23      memory if you know which Ethicon devices you have that</p> <p>24      information for. If you don't, you don't.</p> <p>25      A. And maybe calling out, maybe I'm</p>	<p>1       products and that information is certainly available.</p> <p>2       Q. Now, I had asked you before as to, for</p> <p>3       instance, if the patient had been implanted both with an</p> <p>4       Ethicon sling and an Ethicon Prolift, how the numbers</p> <p>5       would splice out, and I think you testified, number one,</p> <p>6       you'd have to check, but number two, you think it might</p> <p>7       appear in both columns?</p> <p>8       A. Yes, I would anticipate it would appear in both</p> <p>9       columns because, if there was an MDR report for TVT and</p> <p>10      you don't include it in TVT, then that's an inappropriate</p> <p>11      representation of the numbers of reports addressing TVT</p> <p>12      saying for Prolift. It would be most appropriate to</p> <p>13      include that in both places. If we were doing a more</p> <p>14      in-depth analysis and we would define -- and we have done</p> <p>15      these types of analysis before -- we would define how</p> <p>16      many of those there were.</p> <p>17      Q. Did you do that same approach, say, if a</p> <p>18      patient was implanted with both an Ethicon product and a</p> <p>19      Boston Scientific product, would the number appear in</p> <p>20      both columns?</p> <p>21      A. Yes.</p> <p>22      Q. Did Christine make any attempt at determining</p> <p>23      whether or not there were some other concomitant causes</p> <p>24      of the list of adverse events?</p> <p>25      A. Not for this tabulation, no.</p>
Page 47	Page 49
<p>1       misunderstanding the question, so let me clarify. We</p> <p>2       didn't call out and not include those because that would</p> <p>3       be inappropriate not to include them.</p> <p>4       Q. It would lower the numbers quite a bit,</p> <p>5       wouldn't it?</p> <p>6       A. Yes. It doesn't mean -- just because it's</p> <p>7       reported in litigation, it doesn't mean they're not real.</p> <p>8       To not include them would not be an appropriate</p> <p>9       representation of the data. And what was done here is</p> <p>10      present an appropriate representation, an accurate</p> <p>11      representation of the numbers in the MDR reports as</p> <p>12      possible. Calling out is not the term that I would use.</p> <p>13      We have done, for some of the products, that analysis</p> <p>14      where we know how many were reported by attorneys based</p> <p>15      on the information that's in the MDR report.</p> <p>16      Q. Is that in previous reports that you have done</p> <p>17      on those devices or is that a separate?</p> <p>18      A. If I'm recalling correctly, as I sit here</p> <p>19      today, some of the reports may include the number that</p> <p>20      were attorney reported, or at least a reference to the</p> <p>21      fact that some may be attorney reported. I don't recall</p> <p>22      specifically without looking back at my reports whether</p> <p>23      or not we gave an actual number, but I know we have done</p> <p>24      that analysis anticipating, for example, that it would be</p> <p>25      of interest to you. We have done that analysis for some</p>	<p>1       Q. You didn't either?</p> <p>2       A. Not for this tabulation. This is specifically</p> <p>3       as it's described a tally of the total numbers of MDR</p> <p>4       reports that were submitted to FDA for the products of</p> <p>5       the manufacturers listed here.</p> <p>6       Q. Now, for the products listed here for the</p> <p>7       years, do you have any sort of denominator number? For</p> <p>8       instance, do you know how many TVT family of slings were</p> <p>9       sold in 2010?</p> <p>10      MR. KUNTZ: I guess I have to object. That's</p> <p>11      an improper hypothetical. We have asked at least 30</p> <p>12      times for that number from you guys and never been given</p> <p>13      that number. It's an impossibility for her to make the</p> <p>14      calculation.</p> <p>15      BY MS. SUTHERLAND:</p> <p>16      Q. You don't have the number?</p> <p>17      A. I don't.</p> <p>18      MR. KUNTZ: It's impossible. You won't give us</p> <p>19      that number.</p> <p>20      THE WITNESS: No.</p> <p>21      MR. KUNTZ: We have been asking for five years,</p> <p>22      is my point.</p> <p>23      BY MS. SUTHERLAND:</p> <p>24      Q. With respect to the numbers that are listed in</p> <p>25      the columns for Ethicon, do you know all of the types of</p>

## Peggy Pence, Ph.D.

<p style="text-align: center;">Page 50</p> <p>1 events that were listed, such as erosion, pain?</p> <p>2 A. Pain, urinary tract problems.</p> <p>3 Q. Do you have a listing of what they all were for</p> <p>4 in the numbers here?</p> <p>5 A. I have -- if you go back to the TVT report and</p> <p>6 my Prolift report, there's an itemization for those</p> <p>7 specific products for the types of events as well as --</p> <p>8 Can you ask the question again?</p> <p>9 Q. Sure.</p> <p>10 For this exhibit that you put together for the</p> <p>11 supplemental report, do you have a listing of the events</p> <p>12 that are included?</p> <p>13 A. For some of the products, yes, but this is --</p> <p>14 again, I reiterate, this is a tally of all of the MDR</p> <p>15 reports that were submitted for those products. For some</p> <p>16 of these products and for certain of the years, we have</p> <p>17 done a tabulation of the numbers of erosions that were</p> <p>18 reported, the numbers of pain that were reported, the</p> <p>19 numbers of dyspareunia that were reported, the number of</p> <p>20 urinary tract issues that were reported, the number of</p> <p>21 infections that were reported. And our numbers are</p> <p>22 consistent with FDA's representation of what they</p> <p>23 reported they found in the MAUDE database, for example,</p> <p>24 in their 2008 public health notification and their update</p> <p>25 in 2011, their safety communication. And, in fact, I</p>	<p style="text-align: center;">Page 52</p> <p>1 MR. KUNTZ: It will help.</p> <p>2 MS. SUTHERLAND: Yes. If someone else covers</p> <p>3 it, I will definitely make sure it's squared away on what</p> <p>4 we agreed to.</p> <p>5 MR. KUNTZ: For the record, I'll have them file</p> <p>6 that in Ramirez too, if need be.</p> <p>7 MS. SUTHERLAND: If need be.</p> <p>8 BY MS. SUTHERLAND:</p> <p>9 Q. Now, let's go back to your February Prosima</p> <p>10 report.</p> <p>11 Do you need a break or anything? We have been</p> <p>12 going over an hour.</p> <p>13 A. I wouldn't mind.</p> <p>14 MS. SUTHERLAND: Let's go off the record.</p> <p>15 (Recess.)</p> <p>16 BY MS. SUTHERLAND:</p> <p>17 Q. Quickly, Pence Exhibit 2 to your Prosima</p> <p>18 February report is your CV.</p> <p>19 Is that pretty much up to date?</p> <p>20 A. Yes and no. I was looking at this the other</p> <p>21 day that I need to update the address, so the address.</p> <p>22 Q. You still have Newbury Park?</p> <p>23 A. Exactly. We do have the satellite office,</p> <p>24 basically, with my staff working remotely, but that old</p> <p>25 address is no longer accurate. I do need to update that.</p>
<p style="text-align: center;">Page 51</p> <p>1 state that in my reports where we have presented that</p> <p>2 type of information at that level of detail, that what we</p> <p>3 found for the specific products were representative of</p> <p>4 what FDA found across the numbers of manufacturers that</p> <p>5 FDA evaluated and published, for example, in its 2011</p> <p>6 review of the MAUDE database and the literature relevant</p> <p>7 to transvaginal meshes, particularly, pelvic organ</p> <p>8 prolapse for the discussion here today.</p> <p>9 Q. How long has Christine Swanson worked for you?</p> <p>10 A. Over a year, at this point, if I recall</p> <p>11 correctly.</p> <p>12 MS. SUTHERLAND: I'll hand you and attach the</p> <p>13 supplemental report for TVT.</p> <p>14 (Defendant's Exhibit 4 was marked for</p> <p>15 identification by the court reporter.)</p> <p>16 BY MS. SUTHERLAND:</p> <p>17 Q. Is that your supplemental report on TVT and</p> <p>18 TVT-O dated March 2016?</p> <p>19 A. Yes, March 2, 2016.</p> <p>20 MS. SUTHERLAND: You can set that aside. I</p> <p>21 think we're on the same page, that with the Ramirez depo</p> <p>22 coming up in a couple of weeks, that I'll address that</p> <p>23 then.</p> <p>24 MR. KUNTZ: Yes. Are you doing the depo?</p> <p>25 MS. SUTHERLAND: Unless I can get out of it.</p>	<p style="text-align: center;">Page 53</p> <p>1 There are a couple things to add to it. What's here is</p> <p>2 correct.</p> <p>3 Q. What are you adding to it? Presentations?</p> <p>4 A. Not presentations so much as conferences that I</p> <p>5 have attended, continuing education in my profession.</p> <p>6 There are old publications that I located to be added</p> <p>7 that I had forgotten about that I have not added.</p> <p>8 Q. Do any of those old publications have to do</p> <p>9 with pelvic mesh?</p> <p>10 A. No.</p> <p>11 Q. Do they have to do with an implanted device?</p> <p>12 A. Not to my recollection.</p> <p>13 Q. Any of the conferences that you have attended</p> <p>14 that aren't in your CV, did any of those conferences have</p> <p>15 anything to do with pelvic mesh?</p> <p>16 A. No.</p> <p>17 Q. Now, Exhibit 3 to your Prosima report is your</p> <p>18 reliance list, and I wanted to make sure on this, and</p> <p>19 Jeff, you might want to listen to this one part.</p> <p>20 MR. KUNTZ: I'm listening.</p> <p>21 THE WITNESS: Go ahead.</p> <p>22 BY MS. SUTHERLAND:</p> <p>23 Q. I didn't get any reliance lists with the</p> <p>24 supplemental reports, and I wanted to make sure that I</p> <p>25 was not supposed to get any updated reliance list with</p>

## Peggy Pence, Ph.D.

<p style="text-align: center;">Page 54</p> <p>1 the supplemental reports in March.      2 Do you know, Dr. Pence, and then I can talk to      3 Jeff off the record?      4 A. I have the information footnoted in my      5 supplemental report. I didn't provide a reliance list      6 additional to that.      7 Q. I just wanted to make sure I didn't miss it if      8 you had it.      9 A. It's either referenced or footnoted in my      10 report that I relied on for inclusion in the supplemental      11 report.      12 MR. KUNTZ: Let's off the record real quick.      13 MS. SUTHERLAND: Okay.      14 (Recess.)      15 MS. SUTHERLAND: Now we're back on.      16 BY MS. SUTHERLAND:      17 Q. Dr. Pence, you were telling me about your CV.      18 A. Yes. Looking at Exhibit 2, which is my CV, it      19 looks as though this one is not the most updated version,      20 unless I am overlooking it. Like, for example, the      21 selected presentations, October 1, 2013, and selected      22 continuing education, 2013 is the last listed there. And      23 I note that in particular because you asked me about      24 presentations, and for example, I did chair a session at      25 the annual FDA Orange County Regulatory Affairs, OCRA</p>	<p style="text-align: center;">Page 56</p> <p>1 There was -- the Exhibit 2, I apologize, didn't get      2 changed.      3 Q. No worries. That actually helped me out      4 because I had thought that I already asked you about this      5 document. Apparently I have not if this was Boston      6 Scientific.      7 A. Some of them you had at one point asked me      8 about part of these.      9 Q. Just tell me real quickly, these are not all of      10 the RCTs on prolapse repair, are they?      11 A. No.      12 Q. How did you --      13 A. Not to my recollection. These were some of the      14 key ones I identified, and I believe it's stated in my      15 report, between 2008 and 2012.      16 Q. When you say they're one of the key ones, were      17 they of a certain strength or length? If you can, tell      18 me why you denoted them as key.      19 A. When I originally did this, it was back in      20 2014. At this point in time, as I sit here today, I      21 can't recall exactly why I chose these particular ones,      22 except that, of course, they were randomized controlled      23 trials and that, obviously, that's the highest level of      24 evidence. Depending on the quality, it's generally      25 considered the highest level of evidence, but you have to</p>
<p style="text-align: center;">Page 55</p> <p>1 discussion group meeting last year, that would have been      2 2015, and I also, if I recall correctly, 2014. I think      3 this is an older copy.      4 Q. You think you have one that's updated?      5 A. Yes. This is an older copy that was produced,      6 it appears.      7 Q. I'm sure I'll follow up with a request to Jeff      8 to get the updated CV, and if you want to update the      9 address and anything else that you saw, do that for me,      10 please.      11 A. I will do that.      12 Q. Exhibit 5 is a listing of RCTs on prolapse      13 repair; correct?      14 A. Yes.      15 Q. It says at the top, "Randomized controlled      16 clinical trials."      17 Did you pull this from a different report?      18 A. Yes, and that didn't get corrected.      19 Q. Do you know what report you might have pulled      20 Exhibit 5 from?      21 A. Yes.      22 Q. I'm assuming it was Prolift?      23 A. No. Actually, the Prolift report, if I recall      24 correctly, only had five summarized, and in one of my BSC      25 reports, I updated that to include all of those here.</p>	<p style="text-align: center;">Page 57</p> <p>1 evaluate each study individually. And because these were      2 randomized controlled clinical trials with and without      3 mesh, the "with and without mesh" was, of course,      4 important to my consideration of including those in here.      5 Q. Just so I'm clear, I don't know if I asked it      6 this way: Are there other randomized controlled trials      7 that are published and available with and without mesh      8 that are not included in your Exhibit 5 or did you get      9 them all?      10 A. No. Yes, there are.      11 Q. There are other additional RCTs out there on      12 mesh and non-mesh doing a head-to-head comparison?      13 A. Yes.      14 Q. As you sit here today -- I know you did this a      15 while back -- you can't tell me why you picked out these      16 particular studies that are in here?      17 A. I don't recall every reason that I picked those      18 out except for what I just mentioned, because it was back      19 in 2014, but clearly, they were randomized controlled      20 trials, which is a high level of evidence. They were a      21 comparison to without mesh. They were articles that I      22 found referenced in a number of other articles, and so I      23 thought they were representative. That would have been      24 the standard, that they are representative of the      25 literature at that time from 2008 to 2012.</p>

## Peggy Pence, Ph.D.

Page 58	Page 60
<p>1       Q. As you sit here today, do you have any plans to 2 supplement your Prosima or Prolift reports, just as you 3 sit here today?</p> <p>4       A. As I sit here today, I don't have specific 5 plans to supplement my report, but I reserve the right to 6 supplement the report if needed.</p> <p>7       Q. Have you read any of the defense expert records 8 from Wave 1 in the MDL?</p> <p>9       A. Perhaps you can clarify who those were because 10 I don't know specifically. I have read, obviously, 11 defense expert reports over the period of the last couple 12 of years.</p> <p>13      Q. Let me ask it this way: Have you read any 14 defense expert reports in the past month that were dated 15 within the past month?</p> <p>16      MR. KUNTZ: Past week.</p> <p>17      BY MS. SUTHERLAND:</p> <p>18      Q. Past week?</p> <p>19      A. No.</p> <p>20      Q. Now, I caught myself reading your report and 21 your exhibits. I did not see a list of testimony for the 22 past four years.</p> <p>23      Do you have a list of testimony, both 24 deposition and trial?</p> <p>25      A. Yes.</p>	<p>1       reports, do you know how many hours you have billed on 2 that work?</p> <p>3       A. Repeat that again. I'm sorry.</p> <p>4       Q. What I'm trying to limit it to is the recent 5 work you have done on Ethicon products, and as far as I 6 know, that would be your Prosima report, your 7 supplemental Prosima and Prolift report, and your 8 supplemental TTV report.</p> <p>9       Do you know approximately how many hours you 10 put into that work?</p> <p>11      A. I can tell you for the Prosima report, the 12 February 1st, 2016, Prosima report, that I have an 13 invoice ready to be submitted that's a little over 14 \$34,000. I spent approximately 67 hours and Christine 15 has over 13 hours, between 13 and 14 hours, to the best 16 of my recollection as I sit here today. I have not 17 totaled my time yet over the last couple of weeks for the 18 supplemental report for TTV and Prosima and preparation 19 for the deposition.</p> <p>20      Q. Do you have a ballpark of what you think that 21 might be?</p> <p>22      A. As I say, I haven't totaled it. If you're 23 including TTV, it's probably somewhere 60 to 100 hours. 24 Without totaling it, that's my best estimate as I sit 25 here today.</p>
Page 59	Page 61
<p>1       Q. You don't mind getting that to Jeff?</p> <p>2       A. No.</p> <p>3       Q. Along with your updated CV?</p> <p>4       A. No. In fact, I did produce that when we 5 were -- for the February 1st Prosima report, but it 6 wasn't provided to you then?</p> <p>7       Q. I did not see that. Was it written within your 8 report?</p> <p>9       A. No.</p> <p>10      Q. I caught myself reading it.</p> <p>11      A. It was typed.</p> <p>12      Q. It wasn't attached to what I have seen, and I 13 only saw the five exhibits.</p> <p>14      A. I don't include it in my report, but I did 15 provide it to Counsel.</p> <p>16      Q. That's not a problem. We'll get it.</p> <p>17      I did not see in your report where you listed 18 what your hourly rate is.</p> <p>19      Can you tell me what that is?</p> <p>20      A. Yes. It's \$500 an hour.</p> <p>21      Q. And is that both for testimony and review of 22 documents?</p> <p>23      A. Yes.</p> <p>24      Q. For your Prosima report and your supplemental 25 reports, both Prosima, Prolift, and your TTV supplemental</p>	<p>1       Q. Am I correct that you're not offering a 2 manufacturing defect opinion for any Ethicon device?</p> <p>3       A. Can you clarify?</p> <p>4       Q. Yes. For any particular lot or batch that went 5 through, that something went wrong in the manufacturing 6 process. Are you offering any opinion like that for any 7 Ethicon device?</p> <p>8       A. If you're asking me for a specific batch and 9 manufacturing processing, as I sit here today, it's my 10 understanding I won't be asked to offer those kinds of 11 opinions. If you're talking about information with 12 regard to mesh characteristics --</p> <p>13      Q. No, I'm not. I'm talking literally as it's 14 going through the warehouse and something went wrong on 15 the worktable going through the factory.</p> <p>16      A. That specific kind of information I have not 17 been asked to opine on at this point in time.</p> <p>18      Q. I didn't have page numbers on your Prosima 19 report.</p> <p>20      A. There aren't.</p> <p>21      Q. So if you'll flip over to about page 18, and 22 what I'm looking under is, "Prosima Development 23 Challenges and Failures."</p> <p>24      As I understand it, you have five opinions for 25 Prosima set out in your report; correct?</p>

## Peggy Pence, Ph.D.

Page 62	Page 64
<p>1        A. Yes.</p> <p>2        Q. Now, obviously, you and I have talked about</p> <p>3        Prosimma before?</p> <p>4        A. Yes.</p> <p>5        Q. So I'm limiting my questioning to what I have</p> <p>6        not asked you about before, at least to the best of my</p> <p>7        recollection and my review of the Cavness stip, which I</p> <p>8        will confess is quick.</p> <p>9           One thing I want to ask you about under 18,</p> <p>10       "Carey, Slack, Clinical Evaluation of Prosimma Prototype,"</p> <p>11       if you're with me. Underneath there, you note, "The</p> <p>12       disclosure of certain financial interests is the standard</p> <p>13       or required practice for clinical investigators when</p> <p>14       submitting clinical study reports for publication."</p> <p>15       A. Yes.</p> <p>16       Q. Now, if I'm reading that correctly, you were</p> <p>17       not saying that this is some standard that Ethicon</p> <p>18       breached with respect to disclosure of financial</p> <p>19       interests, or are you? Maybe I should ask it that way.</p> <p>20       A. I think the answer to that is both, both the</p> <p>21       authors as well as Ethicon, because --</p> <p>22       Q. That answers the question. Let me ask the next</p> <p>23       question.</p> <p>24       Can you tell me where the standard is written</p> <p>25       that you're saying Ethicon breached with some failure to</p>	<p>1        you talking about just making a disclosure to the</p> <p>2        publication that was going to publish Dr. Carey's</p> <p>3        results?</p> <p>4        A. Well, also, it was not the financial interest.</p> <p>5        There was a poster presentation that was included. And</p> <p>6        now we're talking about FDA, but there was --</p> <p>7        Q. I'll go ahead and tell you, I really don't want</p> <p>8        to talk about FDA today, which I know surprises you and</p> <p>9        me both, but I want to focus on standards other than FDA</p> <p>10       for today.</p> <p>11       A. That's fine. Yes, there was no disclosure in</p> <p>12       the publication and, therefore, it's a matter of people</p> <p>13       reviewing, any reader reviewing an article, being able to</p> <p>14       judge the information in the article in consideration of</p> <p>15       any potential bias by virtue of one of the investigator's</p> <p>16       or more than one investigator's financial interest in a</p> <p>17       product that is being reviewed. That's the whole reason</p> <p>18       for disclosure, so that that information can be taken</p> <p>19       into account by the reviewer.</p> <p>20       Q. With publications, that information is</p> <p>21       generally provided by the investigator; correct?</p> <p>22       A. That is correct. However, Ethicon was very</p> <p>23       heavily involved in the development of this information.</p> <p>24       In fact, you will note that on page 20 in the report -- I</p> <p>25       realize there are no page numbers there -- but page 20,</p>
Page 63	Page 65
<p>1        disclose financial interest?</p> <p>2        A. Yes. Publications, generally, expect any</p> <p>3        disclosure of financial or proprietary interest to be</p> <p>4        disclosed. The FDA 21 CFR Part 54 on financial</p> <p>5        disclosures, an FDA regulation -- and give me just a</p> <p>6        moment.</p> <p>7        Q. Are you looking for the standard?</p> <p>8        A. Yes.</p> <p>9        Q. Are you thinking it's something besides the FDA</p> <p>10       standard that we talked about?</p> <p>11       A. Yes. To the best of my recollection,</p> <p>12       disclosure of proprietary and financial interest is also</p> <p>13       included in international standards, whether it's GHTF or</p> <p>14       ISO, to the best of my recollection as I sit here today.</p> <p>15       Q. You didn't cite any ISO standards in any of</p> <p>16       your Prosimma reports that I saw, did you?</p> <p>17       A. No. If you look at the GHTF documents, a</p> <p>18       number of them do have, in the reference documents, ISO</p> <p>19       standards.</p> <p>20       Q. Do you know which GHTF document you're talking</p> <p>21       about that might have the standard to disclose financial</p> <p>22       interest?</p> <p>23       A. Not to the best of my recollection sitting here</p> <p>24       today. I would have to double check that.</p> <p>25       Q. The disclosure that you're talking about, are</p>	<p>1        that Dr. Robinson noted that BJOG had agreed to publish</p> <p>2        Carey's study, but that it would require a major rewrite.</p> <p>3        And Dr. Robinson, reflecting on the internal team's</p> <p>4        concerns about the large number of patients lost to</p> <p>5        follow up, and that Dr. Carey had submitted the draft</p> <p>6        manuscript without Ethicon's review, remarked, "This</p> <p>7        seems the best of both worlds. We get the chance to</p> <p>8        revise the data, Marcus's wishes to work with the</p> <p>9        clinical team here in developing the manuscript, and we</p> <p>10       have the agreement from the journal that they will</p> <p>11       publish once they are happy with the manuscript."</p> <p>12       Ethicon definitely had involvement.</p> <p>13       Q. I want to be sure that I know the extent of</p> <p>14       your opinion. Is the financial disclosure that you're</p> <p>15       talking about something that should have been made to</p> <p>16       BJOG?</p> <p>17       A. Yes.</p> <p>18       Q. If I'm reading your report correctly --</p> <p>19       A. If we're excluding FDA for this discussion. It</p> <p>20       should have been made to FDA with the poster presentation</p> <p>21       presented to FDA. If we're excluding FDA, then yes.</p> <p>22       Q. Now, the disclosure that we're talking about</p> <p>23       that should have been made to BJOG was the amount paid to</p> <p>24       Dr. Carey?</p> <p>25       A. It should have been that he had a financial</p>

## Peggy Pence, Ph.D.

Page 66	Page 68
<p>1 interest, a consulting relationship, and that the product      2 had been licensed, that he had a proprietary interest in      3 the development of the product.</p> <p>4 Q. It's your understanding that was not done?</p> <p>5 A. Correct. I did not find that the published      6 paper included any disclosure of his financial interest      7 or Ethicon's involvement.</p> <p>8 Q. Do you know if that information was provided to      9 BJOG otherwise? You know, the publication sends their      10 conflict of interest document that goes with the      11 publication itself. Do you know if disclosure was made      12 to BJOG but was not included in the published report?</p> <p>13 A. As I sit here today, I don't recall having seen      14 that.</p> <p>15 Q. Let me turn over to your first opinion that's      16 listed in the report, which is on page 32. I'm going to      17 try to cut through this.</p> <p>18 As I understand it, this opinion focuses on      19 what -- your opinion was not provided to FDA, and had FDA      20 known certain things, it would not have cleared Prosima.</p> <p>21 Is that a fair nutshell?</p> <p>22 A. As I understand your question, yes.</p> <p>23 Q. Let's go to Opinion 2, which is, as I      24 understand it -- let me ask you this: For Opinion 2, if      25 I'm understanding, is it your opinion that there were</p>	<p>1 two-thirds of the way down in that paragraph, you say,      2 "There Ethicon failed to follow the requirement it      3 created for releasing the Prosima onto the market. If      4 Ethicon had followed its own internal requirement related      5 to safety and performance of the Prosima, it never would      6 have been released."</p> <p>7 A. Right.</p> <p>8 Q. The question to you is: What internal      9 requirement of Ethicon are we talking about there, just      10 so I know?</p> <p>11 A. It was the project charter, and it is      12 referenced in my report. Let me just locate it. It's on      13 page 18 of the report, at the very end of the paragraph      14 at the top of the page, "Importantly at the outset of the      15 Project Mint charter."</p> <p>16 Q. I'm not with you yet. I think I'm on 18.</p> <p>17 A. Middle of the page, it has Section B, "Prosima      18 development challenges and failures." At the top of that      19 page, the last sentence of that paragraph, "Importantly      20 at the outset of the Project Mint charter," which was      21 Prosima, for Prosima, what became Prosima, I should say,      22 "Ethicon recognized that if the results of the clinical      23 evaluation performed by the inventor, Dr. Marcus Carey,      24 and his development partner, Dr. Mark Slack of Cambridge,      25 United Kingdom, were not favorable, the project should be</p>
Page 67	Page 69
<p>1 inadequate studies, clinical studies, to support the      2 marketing of Prosima? Is that part of your Opinion 2?</p> <p>3 A. That is part of my Opinion 2, yes.</p> <p>4 Q. Is the second half of your Opinion 2 that after      5 Prosima was marketed, there remained a lack of clinical      6 studies showing its safety and efficacy? And I'll tell      7 you what I'm trying to do here is have a dividing line      8 between premarket and postmarket if we can do that with      9 your opinion.</p> <p>10 A. Give me one moment. Can you repeat your      11 question, please?</p> <p>12 Q. Yes, ma'am.</p> <p>13 If I'm understanding your Opinion 2 correctly,      14 does it cover both premarket studies, which, in your      15 opinion, did not show safety and efficacy of Prosima, and      16 postmarket studies, which did not show safety and      17 efficacy of Prosima?</p> <p>18 A. Yes.</p> <p>19 Q. So let me try to address those in two separate      20 buckets, if I could, just to keep things clear. You and      21 I have already talked about the studies that were      22 conducted back in Cavness. Really, what I'm focusing on      23 here are the standards that you're relying on for your      24 opinions.</p> <p>25 The first question I want to ask you is, about</p>	<p>1 abandoned or the scope changed."</p> <p>2 Q. And you reference there Footnote 40?</p> <p>3 A. Yes.</p> <p>4 Q. Is Footnote 40 the document that supports that      5 sentence?</p> <p>6 A. Yes, Project Mint charter presentation from      7 June of 2005.</p> <p>8 Q. We go on -- and I'm back at page 33 -- "For all      9 medical devices, the internationally accepted standard of      10 care is that a clinical evaluation of the device,      11 including clinical data, show a favorable benefit-risk      12 ratio."</p> <p>13 A. Correct.</p> <p>14 Q. Now, where is that internationally accepted      15 standard of care written?</p> <p>16 A. It's repeated in a variety of documents, but if      17 you look at Exhibit 1 in the supplemental report and you      18 go to the essential principles of safety and performance,      19 for example, to page 3 in that Exhibit 1 of the      20 supplemental report, one of the principles in essential      21 principles of safety and performance -- let me start on      22 the prior page, on page 2, with the very first essential      23 principle of safety and performance that's listed.      24 "Medical devices should be designed and manufactured in      25 such a way that, when used under the conditions and for</p>

## Peggy Pence, Ph.D.

Page 70	Page 72
<p>1 the purposes intended and where applicable, by virtue of      2 the technical knowledge, experience, education or      3 training, and the medical and physical conditions of      4 intended users, they will perform as intended by the      5 manufacturer and not compromise the clinical condition or      6 the safety of patients, provided that any risk which may      7 be associated with their use constitute acceptable risk      8 when weighed against the benefits to the patient and are      9 compatible with a high level of protection of health and      10 safety."</p> <p>11 Q. Where does that come from?</p> <p>12 A. This comes from the final document, Global      13 Harmonization Task Force, Essential Principles of Safety      14 and Performance of Medical Devices.</p> <p>15 Q. That's what I'm going to hand you, Exhibit 10.      16 (Defendant's Exhibit 10 was marked for      17 identification by the court reporter.)</p> <p>18 BY MS. SUTHERLAND:</p> <p>19 Q. Is that a document that sets out the standard      20 that you reference back in your report on page 33? What      21 I want to do is I want to get what all of the standards      22 are. If I have questions about those, I'll come back.</p> <p>23 A. Repeat the last question.</p> <p>24 Q. Yes, ma'am.</p> <p>25 I'm back on page 33. What I'd asked you there</p>	<p>1 which I have marked as Number 10; correct?      2 A. Yes.</p> <p>3 Q. And then you said there are other GHTF guidance      4 documents that also have that same standard?</p> <p>5 A. Well, they reference back to the essential      6 principles of safety and performance, which include a      7 favorable benefit risk. For example, if you go to the      8 clinical evaluation, May 2007.</p> <p>9 Q. You got to slow down. I want to get them all.      10 Tell what that was, May 2007 clinical evaluation?</p> <p>11 A. May 2007, yes.</p> <p>12 MS. SUTHERLAND: I'll mark that as Number 11.      13 I am not going to have all of these. I tried to get all      14 of them that I could.</p> <p>15 (Defendant's Exhibit 11 was marked for      16 identification by the court reporter.)</p> <p>17 BY MS. SUTHERLAND:</p> <p>18 Q. I'm handing you what I marked as Number 11.      19 Is that the second standard that you were just      20 discussing?</p> <p>21 A. Yes.</p> <p>22 Q. Now, is there another one?</p> <p>23 A. For example, in the document -- this is the      24 point I'm trying to make -- the GHTF documents represent      25 a global model that has been accepted internationally for</p>
Page 71	Page 73
<p>1 was, you reference an internationally accepted standard      2 of care in that bottom part of that paragraph.</p> <p>3 A. Yes.</p> <p>4 Q. My question to you is: Is that internationally      5 accepted standard of care that you're referencing      6 contained in what I have now marked as Deposition Exhibit      7 Number 10?</p> <p>8 A. It is contained in here, and also, the      9 risk-benefit information is also. The need for favorable      10 benefit-risk assessment for marketing of a medical device      11 is also referenced in other standards, other GHTF      12 standards.</p> <p>13 Q. What are those?</p> <p>14 A. For example, the --</p> <p>15 Q. Put a pin in that and we'll come back to that.</p> <p>16 For the sentence that you have got written here      17 on page 33 which talks about, "For all medical devices,      18 the internationally accepted standard of care is that a      19 clinical evaluation of the device, including clinical      20 data in the form of clinical studies, literature,      21 clinical experience, must demonstrate that a favorable      22 benefit-risk ratio exists for the device."</p> <p>23 For that sentence, you're saying you look to      24 that standard which is contained in GHTF, Essential      25 Principles of Safety and Performance of Medical Devices,</p>	<p>1 the development of medical devices. For example, if you      2 start with the essential principles of safety and      3 performance, if you look at the clinical evaluation      4 document, Exhibit 11, if you look on page 6, you'll see,      5 under the references, that this document references the      6 essential principles of safety and performance of medical      7 devices. Now, Exhibit 10 happens to be the 2012 update      8 to a 2005 document on essential principles of safety and      9 performance. So you'll see, because the clinical      10 evaluation document was May of 2007, that the essential      11 principles of safety and performance document that it      12 references was the 2005 document.</p> <p>13 There were updates to these documents over the      14 period of the 20 years of the existence of the GHTF, but      15 there's an interrelationship between these documents that      16 support one another in creating this model for a global      17 clinical development. These various standards support      18 the efforts that need to be undertaken to demonstrate      19 conformity to the essential principles of safety and      20 performance.</p> <p>21 So you'll see in this clinical evaluation,      22 Exhibit 11, that one of the documents it references is      23 also the principles of conformity assessment for medical      24 devices, which is another standard, and that that      25 standard also references back to the essential principles</p>

## Peggy Pence, Ph.D.

Page 74	Page 76
<p>1 of safety and performance.</p> <p>2 Q. Did you go back and review the 2005 essential 3 principles?</p> <p>4 A. Yes, I certainly have.</p> <p>5 Q. Did you do that for your opinion in this case?</p> <p>6 A. To the best of my recollection, I did, yes.</p> <p>7 Q. Do you know what the differences are between 8 the 2005 version and the 2012 version?</p> <p>9 A. If I recall correctly, if I'm not confusing the 10 standards, one of the key differences was the inclusion 11 of information relative to in vitro diagnostic devices.</p> <p>12 Q. I'm asking you that based on your phrasing here 13 on page 33 where you say, "For all medical devices, the 14 internationally accepted standard of care is that a 15 clinical evaluation of the device includes clinical data 16 in the form of clinical studies."</p> <p>17 My question to you is: Is it your opinion that 18 all medical devices require clinical data in order to 19 have an analysis of the benefit-risk ratio?</p> <p>20 A. I think I need clarification. Can you point me 21 again to the statement you're referencing?</p> <p>22 Q. Down on page 33, the sentence we have been 23 talking about, where it says, "For all medical devices." 24 It starts over on the left-hand side.</p> <p>25 A. I have it.</p>	<p>1 devices, because we're talking about devices that have 2 been marketed based on similarity to previously marketed 3 devices, the standard allows you to evaluate the 4 literature for similar devices or commercial experience. 5 Hence, that goes to why I looked at the MDR database 6 because that's publicly available information that a 7 manufacturer can look at for competitor products that are 8 similar to look at the clinical experience.</p> <p>9 If looking at that totality of information that 10 is available, one can rely on that based on comparing 11 one's own device to the other devices that are 12 represented in that, when we're talking about a brand-new 13 device. If the manufacturer can substantiate, based on 14 that available information, that there's a favorable 15 benefit-risk ratio, then premarket clinical studies may 16 not be required. Based on distinctions between your 17 device and similar devices --</p> <p>18 Q. I think you answered the question.</p> <p>19 A. -- then clinical studies may be required. As I 20 have testified to before -- I just need to answer this to 21 be complete --</p> <p>22 Q. It sounded pretty complete.</p> <p>23 A. -- then the company has to make a determination 24 that they may need to do clinical studies in order to 25 show that there's a favorable benefit-to-risk ratio.</p>
Page 75	Page 77
<p>1 Q. That's the sentence I'm focusing on.</p> <p>2 A. Yes.</p> <p>3 Q. My question is, if I'm reading that sentence, 4 it reads to me that your opinion is that all medical 5 devices require clinical data, meaning in human use, to 6 have an analysis of the benefit-risk ratio.</p> <p>7 Is that your opinion?</p> <p>8 A. That's what's stated in the standard, but 9 clinical data can be in the form of scientific medical 10 literature and commercial experience as well as clinical 11 studies.</p> <p>12 Q. So for a new device that's coming out where you 13 don't have published medical literature yet and you don't 14 have previous clinical experience because it's a new 15 device, am I understanding your opinion to be that the 16 standard that you're referencing from GHTF is that you 17 have to have a clinical trial in order to analyze that 18 benefit-risk ratio?</p> <p>19 A. No, that's not what the standard says. In 20 analyzing the benefit-to-risk ratio, because we're 21 talking for Class II devices --</p> <p>22 Q. Correct, at least at the time.</p> <p>23 A. We were talking about Class II devices, and 24 then, of course, Class III devices now that they have 25 been reclassified to high risk, but for medium risk</p>	<p>1 Q. I think I can get this as a yes or no.</p> <p>2 Am I correct, Dr. Pence, that the GHTF 3 standards that you and I have talked about don't set out 4 a bright-line rule saying for all medical devices, you 5 have to have clinical data, meaning trials in humans, 6 before you may analyze the benefit-to-risk ratio?</p> <p>7 MR. KUNTZ: Objection to form.</p> <p>8 THE WITNESS: As you stated that, I can't give 9 you yes or no because the clinical data includes -- 10 doesn't include just clinical investigations on a 11 specific device.</p> <p>12 BY MS. SUTHERLAND:</p> <p>13 Q. For my purposes for this question, when I'm 14 talking about clinical data, I'm talking about the 15 company that has the device that they want to market 16 running a clinical trial in humans.</p> <p>17 A. If you're talking about running a clinical 18 trial in humans specifically, if -- again, it's very 19 qualified. One has to do this on an individual device 20 basis to decide whether or not your device -- if other 21 devices for which there is data or which there are data, 22 either in terms of commercial experience and literature, 23 if those data are adequate to substantiate a favorable 24 benefit-risk ratio for your device, considering the 25 differences of your device to those devices on which</p>

## Peggy Pence, Ph.D.

Page 78	Page 80
<p>1 information is available, if you can substantiate a      2 favorable benefit-risk ratio based on such evidence, then      3 you would not have to do clinical trials. But if you      4 can't, then you need to do clinical studies to      5 demonstrate a favorable benefit-risk ratio.</p> <p>6 Q. So no bright-line rule from the GHTF documents      7 saying you always have to run a clinical trial before you      8 can sell a device?</p> <p>9 A. It's a case-by-case basis depending on the      10 differences in the device and whether the information      11 that is already available for other devices or maybe a      12 prior device, and your device is a modification of the      13 prior device, whether the information is --</p> <p>14 Q. It really is yes or no.</p> <p>15 There's no bright-line rule from the GHTF      16 documents you and I have talked about saying you always      17 have to run a clinical trial in humans before you can      18 evaluate the benefit-risk ratio, yes or no?</p> <p>19 MR. KUNTZ: Objection. Asked and answered.</p> <p>20 THE WITNESS: For the reasons I have mentioned      21 you have to evaluate, no, you have to evaluate on an      22 individual basis, case by case.</p> <p>23 BY MS. SUTHERLAND:</p> <p>24 Q. I think we got our yeses and nos mixed up      25 there. Let me try one last time.</p>	<p>1 what I'm looking for. Does that standard set out the      2 size of the clinical trial a manufacturer would have to      3 do?</p> <p>4 A. That's based on statistics. It gives you the      5 principles, and it gives additional references as well,      6 but it gives you the principles for doing a clinical      7 investigation, and it also references other international      8 standards. I mentioned ISO standards and GHTF standards,      9 also referenced ISO standards, and in this document, for      10 example, on page 5, it references ISO 14155-1 and ISO      11 14155-2, both 2003 documents.</p> <p>12 Q. Do those set out the size? Is there something      13 seriously a manufacturer can look at that says I need 50      14 people? 150 people?</p> <p>15 A. That's based on statistics. When you're      16 designing a clinical trial, the standards say you set out      17 your end points, your objectives. And when you're      18 designing a clinical trial, you make a decision as to      19 what kind of a different -- if you're doing a comparison.</p> <p>20 Q. Is it a case-by-case decision, essentially?</p> <p>21 A. Yes, it is, based on what your end point is      22 going to be, and then the statistician determines how      23 many patients need to be included in each arm.</p> <p>24 Q. Is it also a case-by-case decision as to how      25 long you need your study to go?</p>
Page 79	Page 81
<p>1 There is no bright-line rule in the GHTF      2 documents that you and I have talked about saying that a      3 manufacturer always has to run clinical trials in humans      4 before that manufacturer can adequately assess the      5 benefit-risk-ratio; right?</p> <p>6 A. As I understand your question, right, there is      7 no bright-line rule because every product is different,      8 but the bright-line rule is that you must be able to      9 demonstrate a favorable benefit-risk ratio on available      10 evidence.</p> <p>11 Q. You answered my question. I got it.</p> <p>12 Is there a standard that a manufacturer can go      13 to to tell them, if they think they need to run a      14 clinical trial, how to set it up: How many people need      15 to be in it, how long does it need to be, what end      16 points? Is there some written standard that a      17 manufacturer can go to that sets that out for them?</p> <p>18 A. That sets out the foundation, yes. One is the      19 GHTF clinical investigations.</p> <p>20 Q. What standard is that, clinical investigations?</p> <p>21 A. It's in Exhibit 8 under the tab, "Clinical      22 investigations." The title of the document is, "Clinical      23 Investigations," authored by Study Group 5 of the Global      24 Harmonization Task Force, February 12th, 2010.</p> <p>25 Q. For instance, let me give you an example of</p>	<p>1 A. Yes. It depends on the medical device. If      2 you're doing an ocular treatment that's an eye drop, you      3 don't need to follow those patients for their lifetime,      4 for example. If you're doing a permanent implant and a      5 registry study, for example, you would want to follow      6 them as long as possible so you have long-term data.      7 It's very dependent on the product.</p> <p>8 Q. For a permanent implant that a manufacturer      9 would like to get marketed before the passage of a      10 generation of people, is there some sort of standard that      11 sets out how long a clinical trial would need to go to      12 adequately assess the benefit-risk ratio?</p> <p>13 A. There are authoritative bodies that have      14 provided that information with regard to permanent      15 implants.</p> <p>16 Q. Is that a standard I can look at? You're      17 turning to the supplemental report?</p> <p>18 A. I am.</p> <p>19 Q. Exhibit 1?</p> <p>20 A. Yes. I do talk about implantable devices more      21 in the context of labeling in Exhibit 1.</p> <p>22 Can you repeat the question?</p> <p>23 Q. Yes, ma'am. I was wondering is there a      24 standard that sets out a general length of time that a      25 manufacturer who is making a permanent implant would need</p>

## Peggy Pence, Ph.D.

Page 82	Page 84
<p>1 to have follow-up before they can make an analysis of the      2 benefit-risk ratio before marketing? Is there a standard      3 that sets that out for a permanent implant?</p> <p>4 A. As I sit here today, I don't recall having seen      5 a standard that specifically sets out prior to marketing.      6 Again, it depends on a favorable benefit-risk ratio. It      7 depends on whether alternative treatments are available.      8 It's the kind of information that, prior to marketing, a      9 company works out with the regulators. If you look --</p> <p>10 Q. I think you answered my question.</p> <p>11 A. I just want to be complete. If you look at      12 what's -- at minimum a year for short term. If you look      13 at what authoritative bodies are looking at for medium      14 term or long term, it's three to five for medium term and      15 beyond five years for long term.</p> <p>16 Q. Is that FDA that you're talking about that      17 refers to medium term as three to five years and long      18 term as five years or more?</p> <p>19 A. It's not just FDA. It's some of the other      20 authoritative bodies that have looked at information.      21 For example, I believe it's -- I want to say it's NICE,      22 but I have to double check my memory --</p> <p>23 Q. I think you answered the question.</p> <p>24 A. -- that talks about medium is five years and      25 long term is ten years. But it's information that a</p>	<p>1 A. Yes.      2 Q. With respect to --      3 A. If asked, I will.      4 Q. If asked, you will.      5 With respect to that opinion, do you intend to      6 offer an opinion as to how many women should have been      7 enrolled in that study?</p> <p>8 A. Not a specific number of women, no, because I      9 would need to involve a statistician to write out the      10 protocol and the end points.</p> <p>11 Q. That would be a no?</p> <p>12 A. I'd need to provide that to a statistician to      13 give me the numbers that we needed to demonstrate the      14 safety and efficacy end points that we've set out as      15 objectives in the protocol.</p> <p>16 Q. The question was, do you intend to offer an      17 opinion as to the number of women that should have been      18 in a clinical trial for Prosima prelaunch, I think the      19 answer was no?</p> <p>20 A. The answer would be an adequate number to      21 demonstrate safety and performance as outlined in the      22 protocol.</p> <p>23 Q. Do you have a number that you intend to offer      24 to a jury that should have been in some clinical trial      25 before launch?</p>
Page 83	Page 85
<p>1 manufacturer works out with the body that's going to give      2 it authorization to market the product --</p> <p>3 Q. And here in the U.S., that would be the FDA?      4 A. That would be the FDA here in the U.S.      5 -- and then makes a commitment, if that      6 authoritative body that provides authorization for      7 marketing allows them to market on one-year data or      8 two-year data, and that's going to also be dependent on      9 what the results are for that period of time.</p> <p>10 Q. I think you answered the question.</p> <p>11 A. But it will be with the commitment to continue      12 following patients for a certain period of time based on      13 working that out with the authoritative body that      14 provides authorization for marketing.</p> <p>15 Q. When was Prosima put on the market?</p> <p>16 A. Various documentation, if I recall correctly,      17 shows around December of 2009, some show 2010, but in      18 that time frame.</p> <p>19 Q. Now, are you intending to opine to a jury --      20 let me address this just with Prosima first off. Are you      21 intending to opine to a jury that a specific clinical      22 trial should have been conducted on Prosima before it was      23 marketed?</p> <p>24 A. Yes.      25 Q. You have answered my question.</p>	<p>1 A. Without designing the protocol and doing the      2 appropriate statistics to come up with the right number      3 to demonstrate safety and effectiveness based on the end      4 points of the trial, I can't give you a specific number.</p> <p>5 Q. You haven't drafted a protocol to that end,      6 have you, for Prosima?</p> <p>7 A. No, I have not.</p> <p>8 Q. Do you intend to, as you sit here today?</p> <p>9 A. If I were asked to do that, I would. I have      10 not been asked to do that at this point in time.</p> <p>11 Q. Having not been asked to do that, you don't      12 intend to do that right now out of the goodness of your      13 heart, do you?</p> <p>14 A. That's currently not my plan, as I sit here      15 today.</p> <p>16 Q. I have maybe 15 more minutes, so let me get to      17 another opinion. If we can turn to your opinion on      18 labeling. Go back to your full Prosima report. I'm on      19 page 41 and 42, do you see that, Opinion 3 and 4.</p> <p>20 The first thing I want to do is what I did      21 before. For your opinion in Number 3 with respect to      22 looking at that first paragraph. And underneath there,      23 about halfway down the first paragraph, you say, "The      24 globally recognized industry standard for prescription      25 devices, such as Prosima, is for the product IFU to</p>

## Peggy Pence, Ph.D.

Page 86	Page 88
<p>1 contain information necessary," and you go on.      2 A. Yes.      3 Q. Now, that Footnote 146 references the GHTF      4 label and instructions for use document; correct?      5 A. Correct.      6 Q. You wrote that it supersedes previous version      7 in June 2005?      8 A. Yes.      9 Q. Now, is that document that's referenced in 146      10 where the globally recognized industry standard is set      11 out that you reference here in Opinion 3?      12 A. Yes.      13 MS. SUTHERLAND: Let me unload another      14 document. I'm going to hand you what I have marked as      15 Number 12.      16 (Defendant's Exhibit 12 was marked for      17 identification by the court reporter.)      18 BY MS. SUTHERLAND:      19 Q. Am I handing you as Number 12 the documents      20 referenced in Footnote 146?      21 A. Yes.      22 Q. Now, other than what I have just handed you,      23 the GHTF document from 2011 (superseding 2005) is there      24 another document that you're referring to there that sets      25 out any kind of labeling standard on which you rely on</p>	<p>1 listed. That's obviously been updated. I wanted you to      2 know that there were prior standards that didn't just      3 happen in 2011 and 2005. I did include that.      4 Q. Are you telling me that, to some extent,      5 because you read Judge Goodwin's order on the relevancy      6 of documents that came out after a device had been      7 marketed?      8 A. I'm telling you that because any time documents      9 are predicated by other documents, one has to incorporate      10 by reference those prior documents.      11 Q. Does it not have anything to do with Judge      12 Goodwin's order?      13 A. I did see that in the order, yes, but my      14 typical practice is to be comprehensive. And you'll      15 notice that in prior documents that I have referenced SOP      16 documents that were superseded prior to ever reading      17 that.      18 With regard to the rest of the question about      19 is this the sole document I rely on, again, as I      20 described earlier, the interrelationship between these      21 documents. And for example, if you look at Exhibit 10,      22 "The Essential Principles of Safety and Performance of      23 Medical Devices," and you look at the table of contents,      24 B 13 under Section 7 is label and instructions for use.      25 These documents, as I mentioned, are interrelated. If</p>
Page 87	Page 89
<p>1 for your opinion?      2 MR. KUNTZ: I'm going to object. It's vague.      3 BY MS. SUTHERLAND:      4 Q. I can rephrase if you didn't understand.      5 MR. KUNTZ: Related to just the GHTF or all      6 documents?      7 BY MS. SUTHERLAND:      8 Q. My question was a document that sets out the      9 standard in addition to what we have already marked, is      10 there another document that I can look at that sets out      11 the standard for labeling for which you're relying on for      12 your opinion contained in Number 3?      13 A. I want to look up something for a moment, but I      14 want to say that the initial labeling for medical devices      15 standard that predated the 2011 and the 2005 was in      16 February of 2000, and it is included in the binder of      17 GHTF final documents.      18 Q. Was that the first one?      19 A. To the best of my recollection. That's to the      20 best of my recollection, yes.      21 Q. TTVT came out before that, didn't it?      22 A. Yes, it did. I'm just trying to think back.      23 When I told you about current documents, I did include in      24 the binder GHTF documents, some of the predate documents,      25 and I'd have to double check whether the 2000 is still</p>	<p>1 you look at the reference page in that Exhibit 10 on      2 essential principles of safety and performance, you'll      3 see that one of the reference documents is the label and      4 instructions for use for medical devices.      5 Additionally, if you look in what's Exhibit 8,      6 the second tab, the guidance document, principles of      7 conformity assessment for medical devices, you will see      8 that in the documents referenced there, the label      9 instructions for use for medical devices is included.      10 Again, if you look under the third tab also in      11 Exhibit 8, the summary technical documentation for      12 demonstrating conformity to the essential principles of      13 safety and conformance of medical devices (STED), you      14 will see, also, that -- in this case, it references the      15 2005 document, labeling for medical devices is      16 referenced.      17 Q. Multiple documents is what you're telling me?      18 A. Multiple documents, yes.      19 Q. Let me ask you this: You and I have talked      20 before about the blue book memo from 1991; right?      21 A. Yes.      22 Q. And as I understand it, that sets out a      23 standard that you warn of risks that are associated with      24 the device; correct?      25 A. Yes.</p>

Peggy Pence, Ph.D.

Page 90	Page 92
<p>1       Q. Now, is there a similar standard setting out  2 what risks you need to warn about in those GHTF documents  3 that you told me?</p> <p>4       A. Yes, and it's stated in my report. If you look  5 at Exhibit 1 to the supplemental report, at the bottom of  6 page 5, there's a discussion on labeling.  7       If you see at the top of page 6, the standard  8 is that instructions for use should include any residual  9 risk. And importantly, risk is defined as the  10 probability of occurrence of the risk -- a combination of  11 the probability of occurrence of the risk and the  12 severity of the risk. Instructions for use should  13 include any residual risk, warnings, precautions,  14 limitations, or contraindications and measures to be  15 taken. The information included in the instructions for  16 use should be consistent with available clinical data,  17 and all the hazards -- emphasis on all -- all the hazards  18 and other clinically relevant information should be  19 identified appropriately. Any expected and foreseeable  20 side effects, including information to be provided to the  21 patient, should be included in the instructions for use,  22 and any residual risk identified in a risk analysis  23 should be reflected as contraindications or warnings  24 within the labeling.</p> <p>25      Q. Now, would you agree with me that -- you have</p>	<p>1 than with mesh, to correct prolapse; correct?  2       A. Yes.  3       Q. Surgeries, other than with mesh; right?  4       A. Yes.  5       Q. Now, are you familiar enough with those other  6 surgeries to tell me which of the risks listed here in  7 this first section, from hematoma to procedure failure,  8 you do not have if you don't use mesh?  9       A. That you do not have?  10      Q. Right. Are there any risks there listed that  11 you don't have if you don't use mesh?  12       A. Contracture of the mesh itself.  13       Q. Any other ones that you do not have if you  14 don't use mesh?  15      MR. KUNTZ: I'm going to object as vague as to  16 postoperative or long-term.  17      THE WITNESS: In fact, I was just going to say  18 what you have to consider here is not only -- I have  19 pointed that out in multiple reports, not only whether or  20 not they occur with other procedures, but the difference  21 in the frequency of occurrence and the severity of  22 occurrence, the permanency of the occurrence.  23      BY MS. SUTHERLAND:  24       Q. I'll get to that. Right now the only question  25 is -- and I think you answered that -- just out of the</p>
<p style="text-align: center;">Page 91</p> <p>1 risks associated with just surgery itself, and then you  2 have risks associated with the use of the device.  3       Are you following me?  4       A. Yes.  5       Q. Turn to page 35 and 36 of your original Prosima  6 report.  7       A. Yes.  8       Q. Yours looks different than mine.  9       A. I'm sorry.  10      Q. I know we're talking about prolapse in this  11 instance, and you have a list of risks under adverse  12 reactions.  13       Do you see that?  14       A. Yes.  15       Q. And it starts with hematoma and goes through  16 procedure failure.  17       A. Yes.  18       MS. SUTHERLAND: Can we go off for a minute?  19       (Recess.)  20      BY MS. SUTHERLAND:  21       Q. We were looking at the risks you have listed  22 under adverse reactions from hematoma to procedure  23 failure; correct?  24       A. Yes.  25       Q. Now, you understand that there are ways, other</p>	<p style="text-align: center;">Page 93</p> <p>1 first grouping, from hematoma to procedure failure, are  2 there risks there that you don't have if you don't use  3 mesh? And you told me contracture, which you equated to  4 contracture of mesh; correct?  5       A. Yes. I would also add, although pain is listed  6 here -- you have to define what the list is, and it's  7 defined in my report that these were, this particular  8 list, is a list of adverse events that Ethicon had been  9 requested, in this case by FDA, to add to the Prolift.  10      Q. That's not what I asked you. I didn't ask you  11 anything about that.  12       A. We're talking about a specific list.  13       Q. There's no question pending.  14       A. I'm still answering the prior question. You  15 asked me if these were all -- if that was the only one.  16       Pain is listed here because that's how it was  17 presented by FDA, but chronic pain is not listed here,  18 and chronic pain is something, for example, that you find  19 with mesh and typically not with other procedures.  20       Q. Do you have chronic pain at all with other  21 procedures to fix prolapse when you don't use mesh?  22       MR. KUNTZ: Objection.  23      BY MS. SUTHERLAND:  24       Q. Have you seen that in the literature?  25       A. Not in the same fashion.</p>

## Peggy Pence, Ph.D.

Page 94	Page 96
<p>1       Q. Have you seen it in the literature?</p> <p>2       A. To the best of my recollection, it may be a</p> <p>3       possibility, but not to the extent or the severity or the</p> <p>4       life-altering way that you see with mesh.</p> <p>5       Q. The question to wrap up -- assuming, when we</p> <p>6       come back March 24th, I think I can figure the rest of</p> <p>7       this out through the TVT aspect.</p> <p>8       My question to wrap up here before I race to my</p> <p>9       car is, is there a standard that you're relying on that</p> <p>10      tells a manufacturer the risks that the manufacturer has</p> <p>11      to warn about associated with the device versus</p> <p>12      associated just with a procedure --</p> <p>13      MR. KUNTZ: Objection.</p> <p>14      THE WITNESS: I just --</p> <p>15      BY MS. SUTHERLAND:</p> <p>16      Q. -- other than the blue book memo?</p> <p>17      A. I just read a few moments ago.</p> <p>18      Q. Is it the ones you already stated?</p> <p>19      A. Yes. Stating as well that based on my review</p> <p>20      of various documents, that for mesh, separating out the</p> <p>21      procedure from the device, and, in fact, talking about</p> <p>22      the procedure, FDA just had in February a panel meeting</p> <p>23      on reclassification of the instrumentation.</p> <p>24      Q. I didn't ask you anything about</p> <p>25      reclassification.</p>	<p>1                   EXAMINATION</p> <p>2                   BY MR. KUNTZ:</p> <p>3                   Q. I got one question real quick.</p> <p>4                   Dr. Pence, you have also reviewed numerous</p> <p>5                   depositions from Ethicon internal employees, including</p> <p>6                   Medical Directors Weisberg, Dr. Robinson, Pete Hanuel,</p> <p>7                   and regulatory professionals, like Kathryn Breach;</p> <p>8                   correct?</p> <p>9                   A. That's correct.</p> <p>10                  Q. Do they set forth in their testimony what they</p> <p>11                  believe Ethicon or a manufacturer has to set forth in</p> <p>12                  labeling?</p> <p>13                  A. Yes, they do.</p> <p>14                  Q. And to the best of your recollection, what do</p> <p>15                  those individuals say needs to be put in IFUs in labeling</p> <p>16                  with respect to adverse events?</p> <p>17                  A. Adverse reactions that are known, and there's</p> <p>18                  testimony that says all of these adverse reactions were</p> <p>19                  known from the start of the implementation of these</p> <p>20                  products, as well as warnings and contraindications.</p> <p>21                  MR. KUNTZ: No more questions.</p> <p>22                  MS. SUTHERLAND: To be continued.</p> <p>23                  (Time noted: 11:45 a.m.)</p> <p>24</p> <p>25</p>
Page 95	Page 97
<p>1       A. That has to do with the procedure.</p> <p>2       Q. The question is just on the standards.</p> <p>3       A. Separating out the procedure and the device for</p> <p>4       these mesh products, I don't believe it's my opinion you</p> <p>5       can do that, and that all the hazards and any expected</p> <p>6       and foreseeable side effects should be included and any</p> <p>7       residual risk identified according to the standards as I</p> <p>8       discussed them.</p> <p>9       Q. This really is the last question.</p> <p>10      Is there a manufacturer that has met that</p> <p>11      standard in the pelvic mesh arena?</p> <p>12      A. Because I haven't reviewed the information for</p> <p>13      every manufacturer, that type of information for every</p> <p>14      manufacturer in the mesh arena, I'm unable to answer that</p> <p>15      question.</p> <p>16      Q. For the ones you have reviewed, how many have</p> <p>17      you reviewed?</p> <p>18      A. Boston Scientific, Bard, and Ethicon, and</p> <p>19      certain products, not all products for every one of them.</p> <p>20      Q. For the ones you have reviewed, none of them</p> <p>21      have met the standard you just set out?</p> <p>22      A. That's correct.</p> <p>23      MS. SUTHERLAND: That's it.</p> <p>24      ///</p> <p>25      ///</p>	<p>1                   DECLARATION UNDER PENALTY OF PERJURY</p> <p>2                   Case Name: AMSDEN VS. ETHICON</p> <p>3                   Date of Examination: March 9, 2016</p> <p>4                   Job No.: 125666</p> <p>5                   I, PEGGY PENCE, PH.D., hereby certify</p> <p>6                   under penalty of perjury under the laws of the State of</p> <p>7                   _____ that the foregoing is true and correct.</p> <p>8                   Executed this _____ day of _____,</p> <p>9                   20____, at _____.</p> <p>10</p> <p>11</p> <p>12                  PEGGY PENCE, PH.D.</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>

## Peggy Pence, Ph.D.

<p style="text-align: center;">Page 98</p> <p>1 I, KRISTI JOHNSON, CSR No. 12585, Certified      2 Shorthand Reporter, certify;      3 That the foregoing proceedings were taken      4 before me at the time and place therein set forth, at      5 which time the witness declared under penalty of perjury;      6 that the testimony of the witness and all objections made      7 at the time of the examination were recorded      8 stenographically by me and were thereafter transcribed      9 under my direction and supervision;</p> <p>10 That the foregoing is a full, true, and correct      11 transcript of my shorthand notes so taken and of the      12 testimony so given;</p> <p>13 ( ) Reading and signing was requested.      14 ( ) Reading and signing was waived.      15 (X) Reading and signing was not requested.</p> <p>16 I further certify that I am not financially      17 interested in the action, and I am not a relative or      18 employee of any attorney of the parties, nor of any of      19 the parties.</p> <p>20 I declare under penalty of perjury under the      21 laws of California that the foregoing is true and      22 correct.</p> <p>23 Dated this 14th day of March, 2016.      24</p> <hr/> <p>25 KRISTI JOHNSON, CSR No. 12585</p>	<p style="text-align: center;">Page 100</p> <p>1 EXAMINATION ERRATA SHEET      2 Page _____ Line _____ Reason _____      3 From _____ to _____      4 Page _____ Line _____ Reason _____      5 From _____ to _____      6 Page _____ Line _____ Reason _____      7 From _____ to _____      8 Page _____ Line _____ Reason _____      9 From _____ to _____      10 Page _____ Line _____ Reason _____      11 From _____ to _____      12 Page _____ Line _____ Reason _____      13 From _____ to _____      14 Page _____ Line _____ Reason _____      15 From _____ to _____      16 Page _____ Line _____ Reason _____      17 From _____ to _____      18 _____ Subject to the above changes, I certify that the      19 transcript is true and correct      20 _____ No changes have been made. I certify that the      21 transcript is true and correct.      22      23      24      25 PEGGY PENCE, PH.D.</p>
<p style="text-align: center;">Page 99</p> <p>1 EXAMINATION ERRATA SHEET      2 Case Name: AMSDEN VS. ETHICON      Name of Witness: PEGGY PENCE, PH.D.      3 Date of Examination: March 9, 2016      Job No.: 125666      4 Reason Codes: 1. To clarify the record.                        2. To conform to the facts.                        3. To correct transcription errors.      6</p> <p>7 Page _____ Line _____ Reason _____      8 From _____ to _____      9 Page _____ Line _____ Reason _____      10 From _____ to _____      11 Page _____ Line _____ Reason _____      12 From _____ to _____      13 Page _____ Line _____ Reason _____      14 From _____ to _____      15 Page _____ Line _____ Reason _____      16 From _____ to _____      17 Page _____ Line _____ Reason _____      18 From _____ to _____      19 Page _____ Line _____ Reason _____      20 From _____ to _____      21 Page _____ Line _____ Reason _____      22 From _____ to _____      23 Page _____ Line _____ Reason _____      24 From _____ to _____      25</p>	

Peggy Pence, Ph.D.

Page 101

<b>ballpark</b> 60:20	<b>bias</b> 64:15	<b>burned</b> 41:10	<b>certain</b> 13:10 29:20	<b>city</b> 7:14
<b>banks</b> 1:10	<b>billed</b> 60:1	<b>business</b> 10:17	50:16 56:17 62:12	<b>civil</b> 1:9,11,12,14
<b>barbara</b> 3:21 4:5	<b>binder</b> 8:18,20,22	<b>busy</b> 14:15	66:20 83:12 95:19	1:16,18,20,22,24
<b>bard</b> 95:18	8:23 15:2 16:18	<b>butler</b> 7:17	<b>certainly</b> 34:19,23	2:2,4,6,7,9,11,13
<b>base</b> 29:22	17:10 18:4,5,7,14	<b>butlersnow</b> 7:20	35:5 40:24 48:1	2:15,17,19,21,23
<b>based</b> 28:9 35:23	19:22 20:4,9	<b>byrd</b> 1:21	74:4	3:2,4,6,8,10,12,14
37:23 47:14 74:12	37:22 38:4 87:16		<b>certified</b> 98:1	3:16,18,20,22,24
76:2,10,13,16	87:24		<b>certify</b> 97:5 98:2,16	4:2,4,6,8,10,12,14
78:2 80:4,15,21	<b>binders</b> 15:14		100:19,21	4:16,18,20,22,24
83:12 85:3 94:19	16:13		<b>cfr</b> 63:4	5:2,4,6,8,10,12,14
<b>basically</b> 52:24	<b>biology</b> 11:10		<b>chair</b> 54:24	5:16,18,20,22,24
<b>basis</b> 77:20 78:9,22	<b>biotechnology</b>		<b>challenges</b> 61:23	6:2,4,6,8,10,11,13
<b>batch</b> 61:4,8	11:13		68:18	6:15,17,19,21,23
<b>bayview</b> 7:5	<b>bit</b> 47:4		<b>chance</b> 65:7	<b>clarification</b> 74:20
<b>beach</b> 1:12 7:6 10:1	<b>bjog</b> 65:1,16,23		<b>change</b> 23:21	<b>clarify</b> 32:25 47:1
10:15 16:10	66:9,12		<b>changed</b> 23:7 56:2	58:9 61:3 99:4
<b>began</b> 11:25	<b>blue</b> 18:5,13 89:20		69:1	<b>clark</b> 10:13
<b>begins</b> 27:16	94:16		<b>changes</b> 22:11	<b>class</b> 11:6,16 13:2
<b>behalf</b> 7:3	<b>bodies</b> 25:20,22		100:19,21	13:10,12,17 14:1
<b>believe</b> 19:7 20:13	81:13 82:13,20		<b>channel</b> 11:14	14:3,13 75:21,23
29:6 33:25 34:1	<b>body</b> 15:12 41:18		<b>characteristics</b>	75:24
39:21,22 40:4	83:1,6,13		61:12	<b>clear</b> 57:5 67:20
56:14 82:21 95:4	<b>boggs</b> 1:13		<b>charlene</b> 4:23	<b>cleared</b> 66:20
96:11	<b>bollinger</b> 1:15		<b>charleston</b> 1:3	<b>clearly</b> 57:19
<b>benefit</b> 72:7	<b>book</b> 89:20 94:16		<b>chart</b> 42:1 44:7,24	<b>clinical</b> 9:9 11:10
<b>benefitrisk</b> 69:11	<b>boston</b> 9:6 27:4		44:25	14:5,10 19:5,6,23
71:10,22 74:19	28:5 33:25 36:11		<b>charter</b> 68:11,15,20	20:13 55:16 57:2
75:6,18 76:15	36:13 43:7 48:19		69:6	62:10,13,14 65:9
77:24 78:2,5,18	56:5 95:18		<b>charts</b> 38:14	67:1,5 68:22
79:9 81:12 82:2,6	<b>bottom</b> 71:2 90:5		<b>check</b> 13:4 14:2	69:10,11 70:5
<b>benefitriskratio</b>	<b>brain</b> 41:10		19:6,7,13,15 21:1	71:19,19,20,21
79:5	<b>brandnew</b> 76:12		21:3 43:17 48:6	72:8,10 73:3,9,17
<b>benefits</b> 70:8	<b>breach</b> 96:7		63:24 82:22 87:25	73:21 74:15,15,16
<b>benefittorisk</b> 75:20	<b>breached</b> 62:18,25		<b>checking</b> 11:24	74:18 75:5,9,10
76:25 77:6	<b>break</b> 52:11		12:5,19 21:14	75:14,17 76:8,15
<b>best</b> 12:7 19:2,11	<b>bridges</b> 1:17		44:4 46:4	76:19,24 77:5,9
30:12 33:24 34:1	<b>brightline</b> 77:4		<b>cherise</b> 6:1	77:10,14,16,17
34:2 39:21 43:22	78:6,15 79:1,7,8		<b>chose</b> 56:21	78:3,4,7,17 79:3
60:15,24 62:6	<b>bring</b> 14:24		<b>christine</b> 6:18	79:14,19,20,21,22
63:11,14,23 65:7	<b>broader</b> 29:22		17:23 38:20 39:14	80:2,6,16,18
74:6 87:19,20	<b>broken</b> 42:10		43:23,25 48:22	81:11 83:21 84:18
94:2 96:14	<b>brought</b> 15:1,6		51:9 60:14	84:24 90:16
<b>beth</b> 2:1	19:21		<b>chronic</b> 93:17,18	<b>clinically</b> 90:18
<b>better</b> 35:13	<b>bsc</b> 55:24		93:20	<b>close</b> 35:7
<b>betty</b> 3:1	<b>buckets</b> 67:20		<b>circle</b> 7:5	<b>codes</b> 99:4
<b>beyond</b> 82:15	<b>burkhart</b> 1:19		<b>cite</b> 24:5 63:15	<b>cole</b> 2:1

coleman 2:3	83:22	convoluted 35:12	67:14	decided 25:18
college 40:3	cone 2:7	coordinated 18:2	covers 52:2	decision 80:18,20
collins 2:5	conference 12:9,11	copies 15:14 17:15	created 68:3	80:24
colony 7:18	conferences 53:4	20:4,7	creating 73:16	decisions 32:16
colored 16:22	53:13,14	copy 19:21 22:19	cross 19:11	declaration 97:1
column 40:18 44:8	confess 62:8	22:21,23 41:9	csr 7:4 98:1,25	declare 98:20
columns 38:23 44:6	confirm 33:24	55:3,5	curious 36:19	declared 98:5
48:7,9,20 49:25	conflict 66:10	corporation 9:6	current 19:8 20:14	dee 4:21
com 7:15,20	conform 99:4	correct 21:13,14	37:23 38:1,2,6,8	defect 61:2
combination 90:10	conformance 89:13	24:13 26:8,14	87:23	defendant 7:16
combined 39:7	conformity 14:6	29:9,10,13 30:22	currently 11:5	defendants 7:3
40:19 42:12	73:19,23 89:7,12	31:2,9,17 32:2,22	85:14	14:21 16:23 17:17
come 38:22 41:17	confusing 74:9	37:13 42:10,13	cut 66:17	18:8,15 20:19
70:11,22 71:15	confusion 16:5	44:14 53:2 55:13	cv 52:18 53:14	21:8 27:11 51:14
85:2 94:6	consensus 32:16	61:1,25 64:21,22	54:17,18 55:8	70:16 72:15 86:16
comes 14:8 70:12	consider 92:18	66:5 69:13 72:1	59:3	defense 58:7,11,14
coming 51:22 75:12	consideration 57:4	75:22 77:2 86:4,5	cynthia 5:1	define 48:14,15
commencing 7:4	64:14	89:24 91:23 92:1	 <b>D</b>	93:6
commercial 75:10	considered 37:23	92:1 93:4 95:22	<b>d</b> 1:14 7:2 8:1,2,14	defined 90:9 93:7
76:4 77:22	37:25 38:2,8	96:8,9 97:7 98:10	8:16 10:4 97:5,12	definitely 43:16
commitment 83:5	56:25	98:22 99:5 100:20	99:2 100:25	52:3 65:12
83:11	considering 77:24	100:22	<b>data</b> 39:17,25,25	degree 39:23 40:3
communication	consistent 50:22	corrected 55:18	47:9 65:8 69:11	deleon 2:10
50:25	90:16	correctly 11:11	71:20 74:15,18	delineate 17:16
companies 33:19	constitute 70:7	26:1 27:23 28:5	75:5,9 77:5,9,14	delineated 17:11
company 76:23	consulting 66:1	29:6 41:8,12	77:21,21,23 81:6	45:21
77:15 82:9	consumer 33:7	46:16 47:18 51:11	83:7,8 90:16	demonstrate 71:21
comparing 76:10	contain 86:1	55:2,24 62:16	<b>database</b> 31:14	73:18 78:5 79:9
comparison 32:10	contained 25:12	65:18 67:13 74:9	38:16 40:14 41:14	84:13,21 85:3
57:12,21 80:19	71:6,8,24 87:12	83:16	50:23 51:6 76:5	demonstrating
compatible 70:9	containing 8:22,23	<b>counsel</b> 7:9 59:15	<b>date</b> 21:16 22:20	89:12
competitor 76:7	contents 88:23	county 54:25	27:6 36:15 52:19	denise 1:19 2:5
compilation 15:8	context 81:21	couple 14:18 28:22	97:3 99:3	denominator 49:7
complete 76:21,22	conti 2:8	51:22 53:1 58:11	<b>dated</b> 28:2,21 31:7	denoted 56:18
82:11	continue 83:11	60:17	51:18 58:14 98:23	dependent 81:7
completely 46:15	continued 9:1	<b>course</b> 11:12,14,23	<b>dating</b> 25:11	83:8
comprehensive	96:22	12:1 13:7 23:18	<b>dawna</b> 3:13	depending 56:24
29:4,21 88:14	continuing 53:5	23:20 25:17 26:5	<b>day</b> 52:21 97:8	78:9
compromise 70:5	54:22	56:22 57:3 75:24	98:23	depends 81:1 82:6
concerns 28:9 65:4	<b>contract</b> 14:17	<b>court</b> 1:1 14:22	<b>days</b> 23:12	82:7
conclusions 13:22	contracture 92:12	16:24 17:18 18:9	<b>deadline</b> 21:21	depo 14:20 16:3
concomitant 48:23	93:3,4	18:16 20:20 21:9	<b>deal</b> 36:23 39:16	51:21,24
condition 70:5	<b>contraindications</b>	27:12 51:15 70:17	<b>debora</b> 4:19	deposed 22:12 42:8
conditions 69:25	90:14,23 96:20	72:16 86:17	<b>december</b> 83:17	deposition 1:13 7:2
70:3	<b>controlled</b> 55:15	<b>courts</b> 29:20	<b>decide</b> 27:23 77:20	7:6 8:11 20:18
conducted 67:22	56:22 57:2,6,19	<b>cover</b> 12:16,17	21:7 23:14,19	

24:2,3 25:6 27:21 58:24 60:19 71:6 <b>depositions</b> 96:5 <b>described</b> 49:3 88:20 <b>description</b> 41:19 <b>designed</b> 69:24 <b>designing</b> 80:16,18 85:1 <b>destefanoraston</b> 2:12 <b>detail</b> 51:2 <b>determination</b> 76:23 <b>determines</b> 80:22 <b>determining</b> 48:22 <b>developed</b> 32:12 <b>developing</b> 65:9 <b>development</b> 61:22 64:23 66:3 68:18 68:24 73:1,17 <b>device</b> 13:13,18 31:13 53:11 61:2 61:7 69:10 71:10 71:19,22 74:15 75:12,15 76:11,13 76:17 77:11,15,19 77:20,24,25 78:8 78:10,12,12,13 81:1 88:6 89:24 91:2 94:11,21 95:3 <b>devices</b> 9:8,11 12:12,12,13 24:15 46:23 47:17 69:9 69:24 70:14 71:17 71:25 73:1,7,24 74:11,13,18,23 75:5,21,23,24 76:1,1,3,4,11,17 77:4,21,25 78:11 81:20 85:25 87:14 88:23 89:4,7,9,13 89:15 <b>diagnostic</b> 74:11 <b>didnt</b> 23:21 47:2	49:1 53:23 54:5,7 55:18 56:1 61:18 63:15 87:4,21 88:2 93:10 94:24 <b>difference</b> 92:20 <b>differences</b> 74:7,10 <b>different</b> 32:1 36:22 38:14,23 46:13 55:17 79:7 80:19 91:8 <b>dina</b> 2:12 <b>directed</b> 34:10 <b>direction</b> 38:20 41:7,15 98:9 <b>directors</b> 96:6 <b>disband</b> 37:7,14 <b>disbanded</b> 37:1,9 <b>disclose</b> 63:1,21 <b>disclosed</b> 63:4 <b>disclosure</b> 62:12,18 63:3,12,25 64:1 64:11,18 65:14,22 66:6,11 <b>disclosures</b> 63:5 <b>discussed</b> 95:8 <b>discussing</b> 72:20 <b>discussion</b> 41:18 51:8 55:1 65:19 90:6 <b>distinctions</b> 76:16 <b>district</b> 1:1,2,6 <b>dividing</b> 67:7 <b>division</b> 1:3 <b>document</b> 1:7 15:8 25:17 31:4 45:16 56:5 63:20 66:10 69:4 70:12,19 72:23 73:4,5,8,10 73:11,12 79:22 80:9 86:4,9,14,23 86:24 87:8,10 88:19 89:6,15 <b>documentation</b> 8:20 83:16 89:11 <b>documents</b> 8:22,24	14:24 15:4,8,10 15:11 17:21,25 18:11,14,19 30:16 32:12 37:20,21,21 37:24 38:2 59:22 63:17,18 69:16 72:4,24 73:13,15 73:22 78:6,16 79:2 80:11 86:19 87:6,17,23,24,24 88:6,8,9,10,15,16 88:21,25 89:3,8 89:17,18 90:2 94:20 <b>doesnt</b> 19:21 20:15 47:6,7 77:10 <b>doing</b> 11:25 12:14 25:17 28:12 34:10 41:7 48:13 51:24 57:12 80:6,19 81:2,4 85:1 <b>donna</b> 1:9 3:15 4:17 <b>dont</b> 12:5,18 20:13 22:3,20,25 23:3,9 27:6 33:16 34:14 34:22 35:25 36:4 36:9,9,15,18 37:8 39:21,22 40:4,9 41:9 42:10 45:15 45:24 46:4,24,24 47:21 48:10 49:16 49:17 57:5,17 58:4,10 59:1,14 64:7 66:13 75:13 75:13 77:3 81:3 82:4 85:11 92:8 92:11,11,14 93:2 93:2,21 95:4 <b>double</b> 19:5,15 43:17 63:24 82:22 87:25 <b>dr</b> 8:12 10:14 21:16 22:10 23:14,18 24:2 25:6 27:21 54:2,17 64:2 65:1	65:3,5,24 68:23 68:24 77:2 96:4,6 <b>draft</b> 24:23 25:4 65:5 <b>drafted</b> 26:17 31:5 85:5 <b>drake</b> 2:14 <b>drive</b> 10:15 16:10 <b>drop</b> 81:2 <b>drug</b> 13:13,18 <b>drugs</b> 12:10,13 <b>duly</b> 10:5 <b>duplicate</b> 43:8,16 43:24 <b>duplicates</b> 43:20 <b>dyspareunia</b> 41:24 50:19	<b>erosions</b> 50:17 <b>errata</b> 99:1 100:1 <b>errors</b> 99:5 <b>esq</b> 7:12,17 <b>essential</b> 9:7 14:4 69:18,20,22 70:13 71:24 72:5 73:2,6 73:8,10,19,25 74:2 88:22 89:2 89:12 <b>essentially</b> 12:16 34:9 39:3 80:20 <b>establishing</b> 29:3 <b>estimate</b> 60:24 <b>et</b> 1:13,14,18,20,21 1:22,23,24 2:1,1,3 2:3,5,9,10,11,12 2:14,15,17,18,19 2:20,21,23,24,25 <b>e</b> 2:14 8:1 <b>earlier</b> 36:21 88:20 <b>early</b> 25:2 <b>ease</b> 27:16 <b>easily</b> 21:4 <b>education</b> 53:5 54:22 70:2 <b>educational</b> 39:20 <b>effectiveness</b> 85:3 <b>effects</b> 90:20 95:6 <b>efficacy</b> 67:6,15,17 84:14 <b>effort</b> 15:23 <b>efforts</b> 43:8,20,25 73:18 <b>either</b> 15:25 49:1 54:9 77:22 <b>emphasis</b> 90:17 <b>employee</b> 98:18 <b>employees</b> 10:24 96:5 <b>employer</b> 40:10 <b>enrolled</b> 84:7 <b>equal</b> 33:19 36:25 37:3 <b>equated</b> 93:3 <b>erosion</b> 41:23 50:1
---	---	---	---	--

35:15,20 39:6 40:18,25 42:12 44:8 46:1,23 48:4 48:4,18 49:25 60:5 61:2,7 62:17 62:21,25 64:22 65:12 68:2,4,9,22 93:8 95:18 96:5 96:11 97:2 99:2 <b>ethicons</b> 65:6 66:7 <b>evaluate</b> 57:1 76:3 78:18,21,21 <b>evaluated</b> 51:5 <b>evaluation</b> 9:9 14:6 62:10 68:23 69:10 71:19 72:8,10 73:3,10,21 74:15 <b>event</b> 41:19,24 42:11 44:20,22 <b>events</b> 41:14,19 42:3 48:24 50:1,7 50:11 93:8 96:16 <b>evidence</b> 19:5 20:13 29:5 56:24 56:25 57:20 78:2 79:10 <b>exact</b> 22:20 39:8 <b>exactly</b> 11:25 29:17 43:17 52:23 56:21 <b>examination</b> 8:3 10:8 96:1 97:3 98:7 99:1,3 100:1 <b>examined</b> 10:6 <b>example</b> 13:14 33:10,25 38:25 39:6,23 41:8 43:7 45:24 47:24 50:23 51:5 54:20,24 69:19 71:14 72:7 72:23 73:1 79:25 80:10 81:4,5 82:21 88:21 93:18 <b>exclude</b> 29:3 <b>excluding</b> 28:18 65:19,21 <b>executed</b> 97:8	<b>exhibit</b> 8:11,12,14 8:16,18,20,22,23 9:5,7,9,10 14:21 16:18,23 17:9,17 18:8,13,15 19:17 19:18,24 20:2,4 20:18,19 21:7,8 27:11,22 28:3,20 31:16,21,24 32:1 32:14 37:22 38:9 42:9,24 43:12,12 43:21 46:17 50:10 51:14 52:17 53:17 54:18 55:12,20 56:1 57:8 69:17 69:19 70:15,16 71:6 72:15 73:4,7 73:22 79:21 81:19 81:21 86:16 88:21 89:1,5,11 90:5 <b>exhibits</b> 8:9 9:3 16:14 17:1 20:25 21:5,15 23:19 24:3 25:7 30:22 31:2 58:21 59:13 <b>existence</b> 73:14 <b>exists</b> 71:22 <b>expect</b> 63:2 <b>expected</b> 90:19 95:5 <b>experience</b> 31:14 39:25 70:2 71:21 75:10,14 76:4,8 77:22 <b>expert</b> 8:12,14,18 8:21 16:20 20:23 21:21 29:14,18 58:7,11,14 <b>extensive</b> 39:25 <b>extent</b> 12:15,18 38:16 65:13 88:4 94:3 <b>extract</b> 39:10 41:23 <b>eye</b> 81:2	<b>f</b> 2:7 <b>facility</b> 31:13 <b>fact</b> 23:6 25:12 30:8 43:20 47:21 50:25 59:4 64:24 92:17 94:21 <b>factory</b> 61:15 <b>facts</b> 99:4 <b>failed</b> 68:2 <b>failure</b> 25:19 62:25 91:16,23 92:7 93:1 <b>failures</b> 61:23 68:18 <b>fair</b> 13:5 28:16 66:21 <b>familiar</b> 17:6 92:5 <b>family</b> 49:8 <b>far</b> 24:15 38:13 60:5 <b>fashion</b> 93:25 <b>favorable</b> 68:25 69:11 71:9,21 72:7 76:14,25 77:23 78:2,5 79:9 82:6 <b>fda</b> 8:22 11:17 15:6 18:11 28:8,9,13 28:19,24 29:12,19 30:3,9,12,15 35:2 35:10,17 37:12 38:15 39:11 45:11 49:4 51:4,5 54:25 63:4,5,9 64:6,8,9 65:19,20,21,21 66:19,19 82:16,19 83:3,4 93:9,17 94:22 <b>fdas</b> 50:22 <b>february</b> 8:18 16:19 20:24 22:8 22:17,24 23:16 24:5,10 25:2 28:2 28:17 31:16,21,25 32:6 52:9,18 59:5 60:12 79:24 87:16	94:22 <b>feel</b> 25:21 <b>felt</b> 25:5 32:8 <b>figure</b> 94:6 <b>file</b> 23:11 52:5 <b>filings</b> 21:20 <b>final</b> 8:24 18:14 70:12 87:17 <b>financial</b> 62:12,18 63:1,3,4,12,21 64:4,16 65:14,25 66:6 <b>financially</b> 98:16 <b>find</b> 27:17 34:2,4,5 34:9,11 36:23 66:5 93:18 <b>fine</b> 64:11 <b>first</b> 10:5 25:12 26:2 28:3 31:21 33:21 41:6 44:18 <b>fisk</b> 2:16 <b>five</b> 16:22 20:25 21:5 23:5 32:19 32:20 34:13 37:4 49:21 55:24 59:13 61:24 82:14,15,17 82:18,24 <b>fix</b> 93:21 <b>flap</b> 18:6 <b>flip</b> 61:21 <b>focus</b> 64:9 <b>focuses</b> 66:18 <b>focusing</b> 31:1 67:22 75:1 <b>follow</b> 30:7 40:2 55:7 65:5 68:2 81:3,5 <b>followed</b> 68:4 <b>following</b> 1:7 83:12 91:3 <b>follows</b> 10:6 <b>followup</b> 19:6,24 82:1	<b>footnote</b> 17:12 20:1 20:2 69:2,4 86:3 86:20 <b>footnoted</b> 15:9 18:21 54:4,9 <b>footnotes</b> 15:12 18:1 19:14 <b>force</b> 9:7,9,10 11:20 70:13 79:24 <b>foregoing</b> 97:7 98:3 98:10,21 <b>foreseeable</b> 90:19 95:6 <b>forester</b> 2:18 <b>forgotten</b> 53:7 <b>form</b> 71:20 74:16 75:9 77:7 <b>forth</b> 96:10,11 98:4 <b>found</b> 50:23 51:3,4 57:22 <b>foundation</b> 79:18 <b>founding</b> 37:4 <b>four</b> 23:5,8 24:12 24:19 58:22 <b>fox</b> 2:20 <b>frame</b> 32:6,21 33:15 35:17 83:18 <b>fran</b> 2:5 <b>frankly</b> 22:1 <b>free</b> 2:22 8:16 <b>freeman</b> 2:24 <b>frequency</b> 92:21 <b>front</b> 18:6 <b>full</b> 10:12 85:18 98:10 <b>funderburke</b> 3:1 <b>further</b> 23:4 32:11 98:16
<b>G</b>				
<b>general</b> 81:24 <b>generally</b> 56:24 63:2 64:21 <b>generation</b> 81:10 <b>georgilakis</b> 3:3 <b>getting</b> 59:1				

Peggy Pence, Ph.D.

Page 106

<b>ghtf</b> 8:24 11:22 12:2,10,12 13:3,7 13:14,25 15:4 18:14,18 20:5 26:5,6,9,12 27:24 28:3,4,6,8,15,17 28:22 30:13,16,16 32:12,15,20 33:2 33:11 34:13,21 35:4,11,21 36:3,8 36:14,25 37:7,14 37:17,19,20,21 38:2 63:13,17,20 71:11,24 72:3,24 73:14 75:16 77:2 78:6,15 79:1,19 80:8 86:3,23 87:5 87:17,24 90:2 <b>give</b> 13:9,12,19,23 16:8 40:22 41:7 41:15 49:18 63:5 67:10 77:8 79:25 83:1 84:13 85:4 <b>given</b> 23:5 49:12 98:12 <b>gives</b> 80:4,5,6 <b>global</b> 9:7,9,10 11:19 70:12 72:25 73:16 79:23 <b>globally</b> 85:24 86:10 <b>go</b> 18:24 19:12 37:18,23 41:22 50:5 52:9,14 53:21 64:7 66:23 69:8,18 72:7 74:2 79:12,17 80:25 81:11 85:18 86:1 91:18 <b>goes</b> 11:8 32:1 44:23 66:10 76:5 91:15 <b>going</b> 14:13,19 20:17 21:6,19 22:2 27:9,17 52:12 61:14,15	<b>hand</b> 14:19 17:3 18:3 20:17 21:6 27:9 51:12 70:15 86:14 <b>handed</b> 86:22 <b>handing</b> 72:18 86:19 <b>hankins</b> 3:13,15 <b>hanuel</b> 96:6 <b>happen</b> 14:18 45:9 88:3 <b>happens</b> 73:7 <b>happy</b> 65:11 <b>harmonization</b> 9:7 9:9,10 11:20 12:9 12:11 70:13 79:24 <b>harmonize</b> 30:17 <b>harriet</b> 1:12 <b>havent</b> 30:25 60:22 85:5 95:12 <b>hazards</b> 90:17,17 95:5 <b>headtohead</b> 57:12 <b>health</b> 8:15 25:14 25:14 50:24 70:9 <b>hear</b> 43:15 <b>heart</b> 85:13 <b>heather</b> 4:15 <b>heavily</b> 64:23 <b>help</b> 46:22 52:1 <b>helped</b> 56:3 <b>helpful</b> 26:3 32:8 <b>hematoma</b> 91:15 91:22 92:7 93:1 <b>hendrix</b> 3:17 <b>herreranevarez</b> 3:19 <b>high</b> 40:5 57:20 70:9 75:25 <b>highest</b> 56:23,25 <b>highland</b> 7:18 <b>hill</b> 3:21 <b>history</b> 37:2 <b>hadnt</b> 25:25 <b>half</b> 67:4 <b>halfway</b> 85:23	<b>hon</b> 1:5 <b>hooper</b> 3:23 <b>hour</b> 52:12 59:20 86:14 <b>hourly</b> 59:18 <b>hours</b> 60:1,9,14,15 60:15,23 <b>human</b> 75:5 <b>humans</b> 77:5,16,18 78:17 79:3 <b>hundred</b> 40:23,24 <b>hurts</b> 21:3 <b>hypothetical</b> 49:11	65:18 66:16,25 67:7,13,22 68:16 68:16 69:8 70:15 70:25 72:18,24 74:9,12 75:1,3 77:13,14 80:1 85:18 86:14 87:2 87:22 88:8 91:9 92:15 93:14 95:14 <b>imdrf</b> 37:1,10,11 37:12,16,18,20,24 38:6,8 <b>implant</b> 81:4,8,25 82:3 <b>implantable</b> 81:20 <b>implanted</b> 44:2 48:3,18 53:11 <b>implants</b> 81:15 <b>implementation</b> 19:20 96:19 <b>important</b> 25:17,24 57:4 <b>importantly</b> 68:14 68:19 90:9 <b>impossibility</b> 49:13 <b>impossible</b> 49:18 <b>improper</b> 49:11 <b>inadequate</b> 67:1 <b>inappropriate</b> 47:3 48:10 <b>include</b> 11:17,19 13:14 14:9 19:19 20:4,6 28:14 29:23 33:5 47:2,3 47:8,19 48:10,13 55:25 59:14 72:6 77:10 87:23 88:3 90:8,13 <b>included</b> 20:16 25:10 26:7,9 28:4 28:6,7 29:19 33:2 33:7 37:22 50:12 57:8 63:13 64:5 66:6,12 80:23 87:16 89:9 90:15 90:21 95:6
<b>H</b>			
<b>hadnt</b> 25:25 <b>half</b> 67:4 <b>halfway</b> 85:23	<b>history</b> 37:2 <b>holly</b> 4:3 <b>half</b> 10:18 <b>halfway</b> 85:23	<b>hill</b> 3:21 <b>history</b> 37:2 <b>holly</b> 4:3 <b>home</b> 10:18 <b>homes</b> 11:2	<b>history</b> 37:2 <b>holly</b> 4:3 <b>home</b> 10:18 <b>homes</b> 11:2

<b>includes</b> 74:15 77:9 <b>including</b> 11:22 57:4 60:23 69:11 71:19 90:20 96:5 <b>inclusion</b> 54:10 74:10 <b>incorporate</b> 13:21 88:9 <b>independent</b> 33:23 <b>indepth</b> 48:14 <b>index</b> 9:1 <b>individual</b> 13:15,16 77:19 78:22 <b>individually</b> 19:13 57:1 <b>individuals</b> 96:15 <b>industry</b> 28:25 31:4 31:17,22,24 33:5 33:10,18,20 37:3 85:24 86:10 <b>infections</b> 50:21 <b>information</b> 13:10 23:23 25:10,11,13 25:18,22 26:5,6,9 26:12 27:24 28:3 28:6,8,13,15,17 29:20,24 32:11,15 33:16 34:6,11,17 34:22 35:8,23,25 36:21,24 41:6,23 42:4,6,16,19,21 42:25 45:15 46:8 46:24 47:15 48:1 51:2 54:4 61:11 61:16 64:14,18,20 64:23 66:8 71:9 74:11 76:6,9,14 78:1,10,13 81:14 82:8,20,25 86:1 90:15,18,20 95:12 95:13 <b>initial</b> 18:20 87:14 <b>initially</b> 26:1 29:19 35:20 <b>instance</b> 42:11 44:1 45:4 48:3 49:8	79:25 91:11 <b>instruct</b> 13:20 <b>instructions</b> 9:11 86:4 88:24 89:4,9 90:8,12,15,21 <b>instrumentation</b> 94:23 <b>intend</b> 84:5,16,23 85:8,12 <b>intended</b> 70:1,4,4 <b>intending</b> 83:19,21 <b>interest</b> 47:25 63:1 63:3,12,22 64:4 64:16 66:1,2,6,10 <b>interested</b> 98:17 <b>interests</b> 62:12,19 <b>internal</b> 65:3 68:4 68:8 96:5 <b>international</b> 12:9 12:11 29:23,24 30:17 63:13 80:7 <b>internationally</b> 29:1 37:4 69:9,14 71:1,4,18 72:25 74:14 <b>internet</b> 34:5,8 <b>interrelated</b> 88:25 <b>interrelationship</b> 73:15 88:20 <b>interrupt</b> 32:17 <b>inventor</b> 68:23 <b>investigation</b> 80:7 <b>investigations</b> 14:11 77:10 79:19 79:20,22,23 <b>investigator</b> 64:21 <b>investigators</b> 62:13 64:15,16 <b>invoice</b> 60:13 <b>involve</b> 84:9 <b>involved</b> 64:23 <b>involvement</b> 65:12 66:7 <b>isabel</b> 6:3 <b>islands</b> 11:15 <b>isnt</b> 28:20 34:17	<b>iso</b> 63:14,15,18 80:8,9,10,10 <b>issue</b> 41:4 <b>issues</b> 22:3 50:20 <b>itemization</b> 50:6	<b>J</b> <b>j</b> 34:16,16 <b>jane</b> 5:3 <b>janet</b> 5:23 <b>jeff</b> 53:19 54:3 55:7 59:1 <b>jeffrey</b> 7:12 <b>jennifer</b> 5:9,19 <b>jkuntz</b> 7:15 <b>jo</b> 10:13 <b>joann</b> 4:13 <b>job</b> 97:4 99:3 <b>jog</b> 46:22 <b>johnson</b> 4:1 7:3 36:7,7,8,8 98:1,25 <b>joined</b> 37:6 <b>jones</b> 4:3 <b>joseph</b> 1:5 <b>journal</b> 65:10 <b>judge</b> 1:6 9:5 26:16 26:25 27:15 28:18 64:14 88:5,11 <b>jump</b> 45:3 <b>jumps</b> 44:9 <b>june</b> 11:8 69:7 86:7 <b>jury</b> 83:19,21 84:24	<b>K</b> <b>kaiser</b> 4:5 <b>kansas</b> 7:14 <b>karen</b> 1:15 2:18 <b>kari</b> 7:17,20 <b>karyn</b> 2:14 <b>kathryn</b> 96:7 <b>keep</b> 67:20 <b>key</b> 56:14,16,18 74:10 <b>kimberly</b> 6:9 <b>kind</b> 45:10,20 61:16 80:19 82:8	<b>lady</b> 39:13 <b>large</b> 65:4 <b>late</b> 21:20 22:10 25:2 <b>launch</b> 84:25 <b>laws</b> 97:6 98:21 <b>lee</b> 4:11 <b>lefthand</b> 74:24 <b>lehman</b> 4:13 <b>length</b> 56:17 81:24 <b>level</b> 51:2 56:23,25 57:20 70:9 <b>liability</b> 1:6 <b>licensed</b> 66:2 <b>lifealtering</b> 94:4 <b>lifetime</b> 81:3 <b>limit</b> 60:4 <b>limitations</b> 90:14 <b>limiting</b> 62:5 <b>line</b> 67:7 99:7,9,11 99:13,15,17,19,21 99:23 100:2,4,6,8 100:10,12,14,16 <b>list</b> 23:7,11 32:19 36:10 38:1,25 48:24 53:18,25 <b>krystal</b> 6:5 <b>kuntz</b> 7:12 8:5 16:2 21:23,25 23:2 26:19 49:10,18,21 51:24 52:1,5 53:20 54:12 58:16 77:7 78:19 87:2,5 92:15 93:22 94:13 96:2,21	<b>listen</b> 53:19 <b>listening</b> 53:20 <b>listing</b> 16:19 19:9 50:3,11 55:12 <b>lists</b> 53:23 <b>literally</b> 61:13 <b>literature</b> 51:6 57:25 71:20 75:10 75:13 76:4 77:22 93:24 94:1 <b>litigation</b> 1:6 23:6
---	---	--	---	---	---	--

Peggy Pence, Ph.D.

Page 108

28:23,24 45:2,6,8 45:10,14,22 46:9 46:22 47:7 <b>little</b> 60:13 <b>live</b> 10:21 <b>llp</b> 7:17 <b>locate</b> 68:12 <b>located</b> 38:15 53:6 <b>long</b> 4:15 11:7,22 15:18 51:9 79:15 80:25 81:6,11 82:14,15,17,25 <b>longer</b> 12:25 13:3 37:25 52:25 <b>longterm</b> 81:6 92:16 <b>look</b> 19:21 27:7,14 36:23 40:13,16,23 41:2,5,8,11 63:17 69:17 71:23 73:3 73:4 76:7,8 80:13 81:16 82:9,11,12 87:10,13 88:21,23 89:1,5,10 90:4 <b>looked</b> 17:5 40:17 40:21,24 41:3 45:7,9 76:5 82:20 <b>looking</b> 30:21 34:10 42:23 44:7 47:22 52:20 54:18 61:22 63:7 76:9 80:1 82:13 85:22 91:21 <b>looks</b> 18:11 19:19 54:19 91:8 <b>loop</b> 35:7 <b>lost</b> 65:4 <b>lot</b> 12:16 34:17 42:20 61:4 <b>louise</b> 3:7 <b>loustaunau</b> 4:17 <b>lower</b> 47:4 <b>lozano</b> 4:19	<b>maam</b> 25:1 67:12 70:24 81:23 <b>main</b> 15:13 <b>major</b> 65:2 <b>makeup</b> 32:23,25 <b>making</b> 64:1 81:25 <b>management</b> 14:8 14:9 19:20 <b>manufactured</b> 69:24 <b>manufacturer</b> 31:13 36:20 39:9 70:5 76:7,13 79:3 79:4,12,17 80:2 80:13 81:8,25 83:1 94:10,10 95:10,13,14 96:11 <b>manufacturers</b> 38:18 39:5,12 42:15 49:5 51:4 <b>manufacturing</b> 61:2,5,9 <b>manuscript</b> 65:6,9 65:11 <b>march</b> 1:14 7:4 8:19 10:1 16:20 21:11,17 22:21 24:25 25:3 26:13 31:7 32:7 51:18 51:19 54:1 94:6 97:3 98:23 99:3 <b>marcus</b> 68:23 <b>marcuss</b> 65:8 <b>margaret</b> 4:7 <b>marie</b> 1:10 <b>mark</b> 16:18 17:5,9 18:4 68:24 72:12 <b>marked</b> 14:20,21 16:23 17:6,6,17 18:8,15 20:18,19 21:7,8 27:11 30:25 31:1 37:22 51:14 70:16 71:6 72:1,15,18 86:14 86:16 87:9 <b>market</b> 68:3 77:15	83:2,7,15 <b>marketed</b> 67:5 76:2 76:2 81:9 83:23 88:7 <b>marketing</b> 67:2 71:10 82:2,5,8 83:7,14 <b>marking</b> 16:13 27:10 <b>mary</b> 2:7 3:17 5:3 6:11 <b>mass</b> 45:2 <b>masters</b> 11:13 39:18 <b>material</b> 11:23 12:17 13:7,11 26:6 <b>materials</b> 13:19 23:4,10,15 24:4 <b>mathison</b> 9:5 <b>matter</b> 64:12 <b>maude</b> 31:9,11 38:10,15 40:14 46:20 50:23 51:6 <b>mcbryer</b> 4:21 <b>mdl</b> 1:5,8 17:6 28:23 58:8 <b>mdr</b> 38:10 39:10 41:5,6,14,16,18 41:20,22 42:2,14 43:1 44:2,3 45:17 47:11,15 48:9 49:3 50:14 76:5 <b>mdrs</b> 40:20 <b>mean</b> 25:7 32:25 47:6,7 <b>meaning</b> 75:5 77:5 <b>measures</b> 90:14 <b>medical</b> 9:8,11 12:12,12,13 13:13 13:18 69:9,24 70:3,14 71:10,17 71:25 73:1,6,23 74:13,18,23 75:4 75:9,13 77:4 81:1 87:14 88:23 89:4	<b>missouri</b> 7:14 <b>misunderstanding</b> 47:1 <b>mix</b> 33:8 <b>mixed</b> 78:24 <b>model</b> 72:25 73:16 <b>modification</b> 78:12 <b>modifications</b> 25:9 <b>moment</b> 63:6 67:10 87:13 <b>moments</b> 94:17 <b>month</b> 32:6 58:14 58:15 <b>morning</b> 10:10,11 <b>multiple</b> 89:17,18 92:19 <b>myra</b> 1:21
<b>N</b>			
<b>n</b> 8:1 <b>name</b> 10:12 14:1 39:13 97:2 99:2,2 <b>names</b> 39:6,9,9 <b>nancy</b> 3:23 6:16 <b>necessarily</b> 18:21 <b>necessary</b> 86:1 <b>need</b> 14:16 15:3,18 19:7 52:6,7,11,21 52:25 71:9 73:18 74:20 76:20,24 78:4 79:13,14,15 80:13,23,25 81:3 81:11,25 84:9,12 90:2 <b>needed</b> 25:21 58:6 84:13 <b>needs</b> 96:15 <b>never</b> 21:3 28:12 49:12 68:5 <b>new</b> 22:3 23:6,9,21 29:7 75:12,14 <b>newbury</b> 10:20,22 52:22 <b>newport</b> 7:5 10:1 10:15 16:10 <b>nice</b> 82:21			

nix 5:1	<b>objectives</b> 80:17 84:15	67:3,4,9,13,15 74:5,17 75:4,7,15	91:5 99:7,9,11,13 99:15,17,19,21,23	<b>peggy</b> 1:14 7:2 8:2 8:11,12,14,16,19
<b>noemi</b> 5:5	<b>obturator</b> 39:8	84:5,6,17 85:17	100:2,4,6,8,10,12	8:21 10:4,13 97:5
<b>nonmesh</b> 57:12	<b>obvious</b> 43:24	85:17,19,21 86:11	100:14,16	97:12 99:2 100:25
<b>nos</b> 78:24	<b>obviously</b> 24:9 33:2	87:1,12 95:4	<b>pages</b> 17:22,22,24	<b>pelvic</b> 1:5 15:7
<b>notations</b> 45:13	42:20 56:23 58:10	<b>opinions</b> 22:3 23:5	17:24	36:20 38:16 51:7
<b>note</b> 19:19 28:1	62:2 88:1	23:21,22,24,25	<b>paid</b> 65:23	53:9,15 95:11
54:23 62:11 64:24	<b>occur</b> 92:20	25:9,16,19 26:17	<b>pain</b> 50:1,2,18 93:5	<b>penalty</b> 97:1,6 98:5
<b>noted</b> 65:1 96:23	<b>occurred</b> 41:19	27:1,5 28:18 29:5	93:16,17,18,20	98:20
<b>notes</b> 12:6 98:11	42:11 44:22	29:7,12,22,25	<b>pamela</b> 2:22 3:9	<b>pence</b> 1:14 7:2 8:2
<b>notice</b> 7:6 8:11	<b>occurrence</b> 90:10	30:1,4,10,13,14	<b>panel</b> 35:17 94:22	8:11,13,14,16,19
14:20 88:15	90:11 92:21,22,22	30:15 61:11,24	<b>paper</b> 66:6	8:21 10:4,13,14
<b>notification</b> 25:14	<b>ocra</b> 54:25	67:24	<b>paragraph</b> 68:1,13	21:16 27:21 52:17
45:11 50:24	<b>october</b> 54:21	<b>opportunity</b> 22:9	68:19 71:2 85:22	54:2,17 77:2 96:4
<b>november</b> 22:13	<b>ocular</b> 81:2	25:6	85:23	97:5,12 99:2
<b>number</b> 8:10 9:4	<b>offer</b> 37:8 61:10	<b>orange</b> 17:10,20	<b>park</b> 10:20,22	100:25
11:11 14:20 16:18	84:6,16,23	54:25	52:22	<b>pending</b> 93:13
16:21 17:3,5,10	<b>offered</b> 30:2	<b>order</b> 9:5 27:4,6	<b>parkway</b> 7:18	<b>penny</b> 5:11
18:4 20:18 21:7	<b>offering</b> 29:7 61:1	28:18 41:15 74:18	<b>part</b> 11:16,23 12:21	<b>people</b> 45:12 64:12
27:10,22 40:22	61:6	75:17 76:24 88:5	13:9 27:16 28:18	79:14 80:14,14
42:14,22 44:19,23	<b>office</b> 10:19,19 11:1	88:12,13	28:24 29:12 38:6	81:10
46:12 47:19,23	52:23	<b>orders</b> 15:6	53:19 56:8 63:4	<b>percentage</b> 45:3
48:5,6,19 49:7,12	<b>okay</b> 15:22 54:13	<b>organ</b> 15:7 51:7	67:2,3 71:2	<b>perform</b> 70:4
49:13,16,19 50:19	<b>old</b> 40:8 52:24 53:6	<b>organized</b> 22:1	<b>participated</b> 29:2	<b>performance</b> 9:8
50:20 57:22 63:18	53:8	<b>original</b> 20:8 25:11	33:17,18 34:25	14:5 68:5 69:18
65:4 71:7 72:1,12	<b>older</b> 55:3,5	31:15,20 91:5	<b>particular</b> 13:1	69:21,23 70:14
72:18 84:8,17,20	<b>olson</b> 5:3	<b>originally</b> 56:19	29:1 34:6 38:17	71:25 72:6 73:3,6
84:23 85:2,4,21	<b>once</b> 65:11	<b>outline</b> 30:20	39:5,11,12 41:13	73:9,11,20 74:1
86:15,19 87:12	<b>ones</b> 14:1,3 15:5	<b>outlined</b> 84:21	43:18 54:23 56:21	84:21 88:22 89:2
<b>numbers</b> 17:11,12	18:20,22 19:9,15	<b>outset</b> 68:14,20	57:16 61:4 93:7	<b>performed</b> 68:23
17:16 38:23 41:16	32:9 33:12 34:2	<b>outside</b> 16:17 45:2	<b>particularly</b> 51:7	<b>period</b> 58:11 73:14
43:21 45:3 47:4	38:4 40:25 46:3	45:6,8	<b>parties</b> 98:18,19	83:9,12
47:11 48:4,11	46:21 56:14,16,21	<b>overlooking</b> 54:20	<b>partner</b> 68:24	<b>perjury</b> 97:1,6 98:5
49:3,24 50:4,17	76:11 92:13 94:18	<hr/> <b>P</b>	<b>partnership</b> 33:9	98:20
50:18,19,21 51:4	95:16,20	<b>padilla</b> 5:5	37:3	<b>permanency</b> 92:22
61:18 64:25 84:13	<b>oneyear</b> 83:7	<b>page</b> 8:3,10 9:4	<b>passage</b> 81:9	<b>permanent</b> 81:4,8
<b>numerous</b> 96:4	<b>ongoing</b> 32:21	18:1 20:3,3 27:16	<b>patient</b> 48:3,18	81:14,25 82:3
<b>nutshell</b> 66:21	<b>online</b> 34:18	32:13,20 51:21	70:8 90:21	<b>pete</b> 96:6
<hr/> <b>O</b>	<b>operating</b> 20:6	61:18,21 64:24,25	<b>patients</b> 65:4 70:6	<b>ph</b> 1:14 7:2 8:2,14
<b>object</b> 21:24 49:10	<b>opine</b> 61:17 83:19	64:25 66:16 68:13	80:23 81:3 83:12	8:16 10:4 97:5,12
87:2 92:15	83:21	68:14,17,19 69:8	<b>patricia</b> 2:8 5:15	99:2 100:25
<b>objection</b> 26:19	<b>opinion</b> 9:5 23:6,9	69:19,22,22 70:20	6:12	<b>phrasing</b> 74:12
77:7 78:19 93:22	23:10 26:20,25	70:25 71:17 73:4	<b>patterson</b> 5:7	<b>physical</b> 70:3
94:13	27:3,15,23 61:2,6	74:13,22 80:10	<b>paula</b> 2:16 4:9	<b>picked</b> 57:15,17
<b>objections</b> 21:20	65:14 66:15,18,19	85:19 89:1 90:6,7	<b>pays</b> 43:23	<b>pin</b> 71:15
98:6	66:23,24,25 67:2	<b>peek</b> 15:1	<b>pipe</b> 21:25	

<b>place</b> 98:4	13:17 38:24 41:15	32:15 92:20 93:19	31:15,20,25 52:9	<b>Q</b>
<b>places</b> 19:17 48:13	47:10	93:21	52:17 53:17 58:2	<b>qualifications</b>
<b>plaintiff</b> 7:11	<b>presentation</b> 34:24	<b>proceedings</b> 98:3	59:5,24,25 60:6,7	39:15
<b>plaintiffs</b> 21:21	64:5 65:20 69:6	<b>process</b> 32:12 61:6	60:11,12,18 61:18	<b>qualified</b> 77:19
<b>plan</b> 85:14	<b>presentations</b>	<b>processing</b> 61:9	61:22,25 62:3,10	<b>quality</b> 11:10 14:8
<b>plans</b> 58:1,5	41:13 53:3,4	<b>produce</b> 59:4	63:16 66:20 67:2	14:9 56:24
<b>please</b> 10:12 26:23	54:21,24	<b>produced</b> 55:5	67:5,15,17 68:3,5	<b>question</b> 20:8 24:2
55:10 67:11	<b>presented</b> 29:21	<b>product</b> 39:6 45:7	68:17,21,21,21	26:22 35:12 47:1
<b>plus</b> 40:21	41:21 51:1 65:21	45:20 48:18,19	83:15,20,22 84:18	50:8 62:22,23
<b>point</b> 11:2 49:22	93:17	64:17 66:1,3 79:7	85:6,18,25 91:5	66:22 67:11,25
51:10 56:7,20	<b>presenting</b> 29:4	81:7 83:2 85:25	<b>protection</b> 70:9	68:8 70:23 71:4
61:17 72:24 74:20	<b>pretext</b> 35:15	<b>products</b> 1:5 28:4	<b>protocol</b> 84:10,15	74:17 75:3 76:18
80:21 85:10	<b>pretty</b> 16:3 19:13	38:17 39:7,10,11	84:22 85:1,5	77:13 79:6,11
<b>pointed</b> 92:19	52:19 76:22	40:19 42:12,14	<b>prototype</b> 62:10	81:22 82:10,23
<b>points</b> 79:16 80:17	<b>previous</b> 43:4	45:8,23,25 46:1,6	<b>provide</b> 29:21 54:5	83:10,25 84:16
84:10,14 85:4	46:20 47:16 75:14	46:13 47:13 48:1	59:15 84:12	87:8 88:18 92:24
<b>populate</b> 38:23	86:6	49:4,6 50:7,13,15	<b>provided</b> 21:11	93:13,14 94:5,8
<b>position</b> 23:3	<b>previously</b> 28:21	50:16 51:3 60:5	23:22 59:6 64:21	95:2,9,15 96:3
<b>possibility</b> 94:3	39:24 43:13 76:2	76:7 95:4,19,19	66:8,19 70:6	<b>questioning</b> 62:5
<b>possible</b> 47:12 81:6	<b>primarily</b> 18:11	96:20	81:14 90:20	<b>questions</b> 21:18
<b>posted</b> 38:2	<b>principle</b> 69:23	<b>profession</b> 53:5	<b>provides</b> 83:6,14	36:6 40:10 70:22
<b>poster</b> 64:5 65:20	<b>principles</b> 9:7 14:4	<b>professionals</b> 96:7	<b>ps</b> 22:11	96:21
<b>postmarket</b> 19:6,8	19:21 20:6 69:18	<b>project</b> 13:16 68:11	<b>public</b> 50:24	<b>quick</b> 15:22 16:3
19:23 20:15 67:8	69:20,21 70:13	68:15,20,25 69:6	<b>publication</b> 62:14	20:15 54:12 62:8
67:16	71:25 72:6 73:2,6	<b>prolapse</b> 15:7	64:2,12 66:9,11	96:3
<b>postoperative</b>	73:8,11,19,23,25	24:16 51:8 55:12	<b>publications</b> 15:12	<b>quickly</b> 15:20 16:6
92:16	74:3 80:5,6 88:22	56:10 91:10 92:1	53:6,8 63:2 64:20	18:25 19:13 52:17
<b>potential</b> 64:15	89:2,6,12	93:21	<b>publicly</b> 76:6	56:9
<b>powerpoint</b> 11:24	<b>printed</b> 16:1	<b>prolift</b> 21:12 24:12	<b>publish</b> 64:2 65:1	<b>quite</b> 47:4
12:6	<b>prior</b> 13:17 22:17	24:19,21 25:12	65:11	<b>R</b>
<b>practice</b> 62:13	22:22 23:22,24	26:2,7,10,13	<b>published</b> 51:5	<b>r</b> 1:5
88:14	24:4 28:22 46:16	28:13,13,15 29:8	57:7 66:5,12	<b>race</b> 94:8
<b>pratt</b> 6:22	69:22 78:12,13	30:2,10 31:1 41:9	75:13	<b>ramirez</b> 51:21 52:6
<b>precautions</b> 90:13	82:5,8 88:2,10,15	41:11,21 42:5,8	<b>pull</b> 41:15 42:21	<b>randomized</b> 55:15
<b>predate</b> 87:24	88:16 93:14	43:4 44:1 48:4,12	55:17	56:22 57:2,6,19
<b>predicted</b> 87:15	<b>probability</b> 90:10	50:6 55:22,23	<b>pulled</b> 42:19 46:21	<b>rate</b> 59:18
88:9	90:11	58:2 59:25 60:7	55:19	<b>ratio</b> 69:12 71:22
<b>predominantly</b>	<b>probably</b> 16:1	93:9	<b>purpose</b> 30:17	74:19 75:6,18,20
19:16	18:24 44:5 60:23	<b>proposed</b> 15:6	<b>purposes</b> 70:1	76:15,25 77:6,24
<b>preface</b> 35:15	<b>problem</b> 59:16	<b>proprietary</b> 63:3	77:13	78:2,5,18 79:9
<b>prelaunch</b> 84:18	<b>problems</b> 13:22	63:12 66:2	<b>pursuant</b> 7:6	81:12 82:2,6
<b>premarket</b> 67:8,14	50:2	<b>proxima</b> 8:18 15:9	<b>put</b> 14:13 16:12	<b>rcts</b> 55:12 56:10
76:15	<b>procedure</b> 91:16,22	16:19 17:7,8	17:23 21:19 34:24	57:11
<b>preparation</b> 60:18	92:7 93:1 94:12	18:19 20:24 21:12	44:19 45:20 50:10	<b>reactions</b> 91:12,22
<b>prescription</b> 85:24	94:21,22 95:1,3	22:24 24:9,19	60:10 71:15 83:15	96:17,18
<b>present</b> 13:10,11	<b>procedures</b> 20:6	28:1,7,15,17 31:1	96:15	

<b>read</b> 41:22 42:20 58:7,10,13 88:5 94:17	34:1,3 39:22 43:22 53:12 56:13 60:16 62:7 63:11	<b>regulatory</b> 29:14 29:18 33:3,8,9 54:25 96:7	22:6,24 23:17,21 24:6,8,10,24 25:12,23 26:2,4,7	55:25 58:2,11,14 59:25 60:1 62:14 63:16 92:19
<b>reader</b> 64:13	63:14,23 74:6	<b>reiterate</b> 50:14	26:10,14,18 28:2	<b>represent</b> 72:24
<b>reading</b> 13:11 58:20 59:10 62:16 65:18 75:3 88:16 98:13,14,15	87:19,20 94:2 96:14	<b>related</b> 1:7 13:13 13:18,19 68:4 87:5	28:4,6,7,17,22 30:21,24,25 31:9 31:15,16,20,25	<b>representation</b> 33:20 47:9,10,11 48:11 50:22
<b>reads</b> 75:4	<b>record</b> 23:2 45:13 52:5,14 54:3,12 99:4	<b>relationship</b> 66:1	32:2,4,14 38:10	<b>representative</b> 33:18 51:3 57:23 57:24
<b>ready</b> 60:13	<b>recorded</b> 98:7	<b>relative</b> 74:11 98:17	41:9,11,20,21,22 42:5,8,9 43:18	<b>representatives</b> 33:5,7
<b>real</b> 47:7 54:12 56:9 96:3	<b>records</b> 58:7	<b>released</b> 68:6	44:20 45:18 47:15	<b>represented</b> 33:10 33:11 34:19 43:21 76:12
<b>realize</b> 64:25	<b>reference</b> 15:19 24:12 27:16 38:1	<b>releasing</b> 68:3	48:9 50:5,6,11	<b>request</b> 55:7
<b>realized</b> 28:12	38:16 47:20 63:18	<b>relevancy</b> 88:5	51:13,17 52:10,18	<b>requested</b> 93:9 98:13,15
<b>really</b> 64:7 67:22 78:14 95:9	69:2 70:20 71:1 72:5 86:11 88:10 89:1,3	<b>relevant</b> 12:10 28:14 29:1 51:6 90:18	53:17 54:5,10,11 55:17,19,23 56:15 58:5,6,20 59:5,8	<b>requesting</b> 25:15
<b>reason</b> 37:8 46:19 57:17 64:17 99:4 99:7,9,11,13,15 99:17,19,21,23 100:2,4,6,8,10,12 100:14,16	<b>referenced</b> 15:5,11 15:12 17:25 19:16 19:24 20:14 54:9 57:22 68:12 71:11 80:9 86:9,20 88:15 89:8,16	<b>reliance</b> 23:4,11 53:18,23,25 54:5	59:14,17,24 60:6 60:7,8,11,12,18	<b>require</b> 65:2 74:18 75:5
<b>reasons</b> 41:4 78:20	<b>references</b> 73:5,5 73:12,22,25 80:5 80:7,10 86:3 89:14	<b>relied</b> 29:12 38:5 54:10	61:19,25 64:24 65:18 66:12,16	<b>required</b> 62:13 76:16,19
<b>rebecca</b> 6:22	<b>referencing</b> 19:12 71:5 74:21 75:16	<b>relies</b> 28:25	68:12,13 69:17,20	<b>requirement</b> 68:2,4 68:9
<b>recall</b> 11:11 12:5 12:18 13:24 22:13 22:20,25 26:1 27:6,15 34:14 36:4,15,18 46:16 46:21 47:21 51:10 55:2,23 56:21 57:17 66:13 74:9 82:4 83:16	<b>referring</b> 86:24	<b>rely</b> 28:11,19 76:10 86:25 88:19	70:20 81:17 85:18 90:4,5 91:6 93:7	<b>requirements</b> 19:8 20:14
<b>recalling</b> 28:5 41:12 47:18	<b>references</b> 73:5,5 73:12,22,25 80:5 80:7,10 86:3 89:14	<b>relying</b> 22:7 30:3,9 67:23 87:11 94:9	<b>reported</b> 38:15 41:14,20 42:4	<b>research</b> 13:16 33:24
<b>received</b> 25:14	<b>referencing</b> 19:12 71:5 74:21 75:16	<b>remained</b> 67:5	44:20,23 47:7,14	<b>reserve</b> 58:5
<b>recess</b> 52:15 54:14 91:19	<b>referring</b> 86:24	<b>remarked</b> 65:6	47:20,21 50:18,18	<b>residual</b> 90:8,13,22 95:7
<b>reclassification</b> 15:6 94:23,25	<b>reflect</b> 17:11 29:22	<b>remember</b> 15:15 46:4	50:19,20,21,23	<b>resource</b> 13:19
<b>reclassified</b> 75:25	<b>reflected</b> 90:23	<b>reporter</b> 14:22	<b>reporter</b> 14:22	<b>respect</b> 36:7 49:24 62:18 84:2,5 85:21 96:16
<b>recognized</b> 25:8 68:22 85:24 86:10	<b>reflecting</b> 65:3	<b>remind</b> 11:9 20:12	16:24 17:18 18:9	<b>responsibilities</b> 20:5
<b>recognizing</b> 29:19	<b>regard</b> 22:10 61:12	<b>remotely</b> 10:25	18:16 20:20 21:9	<b>rest</b> 88:18 94:6
<b>recollection</b> 12:8 19:2,11 33:25	81:14 88:18	<b>reflect</b> 17:11 29:22	27:12 51:15 70:17	<b>result</b> 26:3
	<b>regarding</b> 8:14,16	<b>repair</b> 1:5 15:7 55:13 56:10	72:16 86:17 98:2	<b>results</b> 64:3 68:22 83:9
	29:8 32:15	<b>repeat</b> 26:23 31:18	<b>reports</b> 23:23 24:12	<b>returned</b> 15:17,20
	<b>regards</b> 25:10	60:3 67:10 70:23	24:16,22 25:11,25	<b>review</b> 13:9,20 19:7 20:14,15 22:9
	<b>registry</b> 81:5	81:22	27:24 29:9,11	25:6 26:16 27:3
	<b>regulation</b> 63:5	<b>repeated</b> 69:16	30:2,11 38:5,10	
	<b>regulations</b> 11:17	<b>rephrase</b> 87:4	38:14 39:10 40:13	
	28:8,19 29:13	<b>report</b> 8:12,14,16	40:20 41:4,5,6,17	
	30:3,9,13,15	8:19,19,21,21	41:18 42:2,14	
	<b>regularizers</b> 33:20	13:23 15:5,9,13	43:1,4,5,6,9 44:9	
	37:2,4,11 82:9	16:20,20 17:22,23	44:13,16 45:5,5	
		17:24,25 18:19,21	45:14 46:7,9,16	
		18:23 19:10,12,25	47:11,16,19,22	
		20:10,23 21:12,16	48:11 49:4 50:15	
			51:1 53:24 54:1	

51:6 59:21 62:7 65:6 74:2 94:19 <b>reviewed</b> 25:5 26:25 27:8,18,19 27:20,21 41:4,5 64:17 95:12,16,17 95:20 96:4 <b>reviewer</b> 64:19 <b>reviewing</b> 27:15 64:13,13 <b>revise</b> 65:8 <b>revisions</b> 25:9 <b>rewrite</b> 65:2 <b>reyes</b> 5:9 <b>rhynehart</b> 5:11 <b>ridgeland</b> 7:19 <b>right</b> 19:10 33:4 35:2 36:11 38:12 40:6 44:16 45:19 58:5 68:7 79:5,6 85:2,12 89:20 92:3,10,24 <b>risk</b> 19:20 25:10 70:6,7 72:7 75:25 75:25 90:9,9,10 90:11,12,13,22,22 95:7 <b>riskbenefit</b> 71:9 <b>risks</b> 89:23 90:2 91:1,2,11,21 92:6 92:10 93:2 94:10 <b>robin</b> 1:17 <b>robinson</b> 65:1,3 96:6 <b>ocio</b> 3:19 <b>roles</b> 20:5 <b>rose</b> 3:5 <b>ruebel</b> 5:13 <b>ruiz</b> 5:15 <b>rule</b> 8:12 77:4 78:6 78:15 79:1,7,8 <b>rules</b> 21:25 23:11 <b>ruling</b> 26:16 <b>run</b> 78:7,17 79:3,13 <b>running</b> 19:14 77:16,17	<b>S</b> <b>s</b> 1:6 29:2,2,18 83:3 83:4 <b>safety</b> 9:7 14:4 45:10 50:25 67:6 67:15,16 68:5 69:18,21,23 70:6 70:10,13 71:25 72:6 73:2,6,8,11 73:19 74:1 84:14 84:21 85:3 88:22 89:2,13 <b>sandra</b> 6:20 <b>satellite</b> 10:19 11:1 52:23 <b>saw</b> 20:9 36:2 55:9 59:13 63:16 <b>saying</b> 18:2 23:7 30:14 46:7 48:12 62:17,25 71:23 77:4 78:7,16 79:2 <b>says</b> 55:15 74:23 75:19 80:13 96:18 <b>school</b> 40:5 <b>scientific</b> 9:6 27:4 28:6 34:1 36:11 36:13 43:7 48:19 56:6 75:9 95:18 <b>scope</b> 26:17 27:1,4 69:1 <b>scrape</b> 16:17 <b>search</b> 38:19,22 39:1,4 41:17 <b>searches</b> 34:10,12 46:20 <b>searching</b> 34:5 <b>second</b> 67:4 72:19 89:6 <b>section</b> 32:13,13 37:20 68:17 88:24 92:7 <b>secure</b> 39:8 <b>see</b> 18:2 20:3 27:18 34:11 37:19,24 41:12 44:9,10 58:21 59:7,17	73:4,9,21 85:19 88:13 89:3,7,14 90:7 91:13 94:4 <b>seeing</b> 34:14 45:4 <b>seen</b> 45:3,5,9 59:12 66:13 82:4 93:24 94:1 <b>selected</b> 54:21,21 <b>sell</b> 78:8 <b>sends</b> 66:9 <b>sense</b> 29:16 <b>sentence</b> 68:19 69:5 71:16,23 74:22 75:1,3 <b>separate</b> 17:20 47:17 67:19 <b>separately</b> 21:4 <b>separating</b> 94:20 95:3 <b>seriously</b> 80:13 <b>session</b> 54:24 <b>set</b> 29:8 30:10 36:24 43:4 51:20 61:25 77:3 79:14 80:1,12,16 84:14 86:10 95:21 96:10 96:11 98:4 <b>sets</b> 70:19 79:17,18 81:11,24 82:3,5 86:24 87:8,10 89:22 <b>setting</b> 90:1 <b>severity</b> 90:12 92:21 94:3 <b>sharon</b> 1:13,23 <b>sheet</b> 99:1 100:1 <b>sherry</b> 2:20 <b>shes</b> 23:5,7 40:11 <b>shipped</b> 16:9 <b>shirley</b> 2:24 <b>short</b> 82:12 <b>shorthand</b> 98:2,11 <b>show</b> 67:15,16 69:11 76:25 83:17 <b>showing</b> 35:8 67:6 <b>shows</b> 41:23 83:17 50:7 51:3 58:4	<b>shultis</b> 5:17 <b>side</b> 17:11 74:24 90:20 95:6 <b>signing</b> 98:13,14,15 <b>sikes</b> 5:19 <b>similar</b> 27:19,23 76:4,8,17 90:1 <b>similarity</b> 76:2 <b>sit</b> 12:19 19:2 22:25 26:1 33:13 34:3 34:15,22 36:1,4,9 36:15,18 39:22 <b>sitting</b> 63:23 <b>sixth</b> 12:1 13:1 <b>size</b> 80:2,12 <b>slack</b> 62:10 68:24 <b>slides</b> 11:24 12:6 <b>sling</b> 39:7 40:18 42:12 44:8 48:4 <b>slings</b> 49:8 <b>slow</b> 72:9 <b>smith</b> 5:21,23 <b>snow</b> 7:17 <b>sold</b> 49:9 <b>sole</b> 88:19 <b>somewhat</b> 31:25 <b>son</b> 40:12 <b>sop</b> 88:15 <b>sorry</b> 12:21 19:23 31:18 60:3 91:9 <b>sort</b> 37:17 49:7 81:10 <b>sounded</b> 76:22 <b>southern</b> 1:2 <b>speaking</b> 14:7 <b>specific</b> 12:1 13:8 13:25 33:15,19 34:22 36:21 37:8 <b>shows</b> 41:23 83:17 50:7 51:3 58:4	61:8,16 77:11 83:21 84:8 85:4 93:12 <b>specifically</b> 12:19 14:2 19:18 22:25 27:7 33:13,17 34:10,14 36:4 40:9 46:4 47:22 49:2 58:10 77:18 82:5 <b>spent</b> 60:14 <b>splice</b> 48:5 <b>springer</b> 6:1 <b>squared</b> 52:3 <b>stacy</b> 5:17 <b>staff</b> 17:7 38:21 41:7,15 52:24 <b>standard</b> 29:24 57:24 62:12,17,24 63:7,10,21 69:9 69:15 70:19 71:1 71:5,18,24 72:4 72:19 73:24,25 74:14 75:8,16,19 76:3 79:12,16,20 80:1 81:10,16,24 82:2,5 85:24 86:10,25 87:9,11 87:15 89:23 90:1 90:7 94:9 95:11 95:21 <b>standards</b> 28:11,25 29:3,4,17,19,23 30:18 31:4,17,22 31:25 63:13,15,19 64:9 67:23 70:21 71:11,12 73:17 74:10 77:3 80:8,8 80:8,9,16 88:2 95:2,7 <b>stands</b> 31:12 <b>stapled</b> 21:4 <b>start</b> 11:5 69:21 73:2 96:19 <b>starting</b> 32:13 <b>starts</b> 11:6 74:24
--	---	---	--	--

91:15 <b>state</b> 11:13 51:1 97:6 <b>stated</b> 23:20 56:14 75:8 77:8 90:4 94:18 <b>statement</b> 37:17 74:21 <b>states</b> 1:1 29:15 <b>stating</b> 94:19 <b>statistician</b> 80:22 84:9,12 <b>statistics</b> 80:4,15 85:2 <b>sted</b> 89:13 <b>stenographically</b> 98:8 <b>stick</b> 16:16 44:3,8 <b>sticker</b> 16:16 <b>stickers</b> 16:12 <b>stip</b> 62:7 <b>stored</b> 42:16 <b>street</b> 16:8 <b>strength</b> 56:17 <b>students</b> 11:12 <b>studies</b> 19:6,24 57:16 67:1,1,6,14 67:16,21 71:20 74:16 75:11 76:15 76:19,24 78:4 <b>study</b> 32:19,20,24 33:22 34:13 35:11 36:16,22 57:1 62:14 65:2 79:23 80:25 81:5 84:7 <b>subject</b> 100:19 <b>submitted</b> 39:11 49:4 50:15 60:13 65:5 <b>submitting</b> 62:14 <b>substantiate</b> 76:13 77:23 78:1 <b>substantiates</b> 29:25 <b>substantiation</b> 25:16 <b>suite</b> 7:5,13,18	<b>sum</b> 43:3 <b>summarized</b> 55:24 <b>summary</b> 89:11 <b>superseded</b> 88:16 <b>supersedes</b> 86:6 <b>superseding</b> 86:23 <b>supervision</b> 98:9 <b>supplement</b> 16:25 17:1 24:20 28:12 32:7 42:9 58:2,5,6 <b>supplemental</b> 8:14 8:16,19,21 16:20 19:25 21:12 22:6 23:10,11,17,20,22 24:5,8,21,23 25:23 26:13,18 30:21,24,25 32:1 32:4,14 38:10 50:11 51:13,17 53:24 54:1,5,10 59:24,25 60:7,8 60:18 69:17,20 81:17 90:5 <b>supplementary</b> 32:15 <b>supplements</b> 16:22 <b>supplied</b> 26:13 <b>support</b> 13:11 23:4 23:10 29:5,12 30:3,9,13 34:11 67:1 73:16,17 <b>supported</b> 30:14,16 <b>supporting</b> 8:20 <b>supportive</b> 23:24 25:8,19 <b>supports</b> 69:4 <b>supposed</b> 53:25 <b>sure</b> 13:5 15:18,22 15:24 16:17 19:2 21:1,15 32:11 33:1 50:9 52:3 53:18,24 54:7 55:7 65:13 <b>surgeries</b> 92:3,6 <b>surgery</b> 91:1 <b>surprises</b> 64:8	<b>surveillance</b> 19:8 20:15 <b>susan</b> 3:11 6:7 <b>suspect</b> 12:7,13 <b>sutherland</b> 7:17,20 8:4 10:9 14:19,23 16:7,16 17:2,9,14 17:19 18:10,13,17 20:17,21 21:6,10 21:18,24 22:5 23:13 26:21 27:9 27:13 49:15,23 51:12,16,20,25 52:2,7,8,14,16 53:22 54:13,15,16 58:17 70:18 72:12 72:17 77:12 78:23 86:13,18 87:3,7 91:18,20 92:23 93:23 94:15 95:23 96:17 97:19 98:1 <b>swanson</b> 38:21 39:14 51:9 <b>swint</b> 6:3 <b>sworn</b> 10:5 <b>syllabus</b> 14:12 <b>symbion</b> 42:17 <b>system</b> 1:5 <b>systems</b> 8:18 14:8 14:10 16:19	<b>T</b> <b>tab</b> 79:21 89:6,10 <b>table</b> 41:16 88:23 <b>tabs</b> 16:21,22,22 17:10,15,20 <b>tabular</b> 41:13 <b>tabulate</b> 42:21 <b>tabulation</b> 41:16,20 42:2,3,13 43:2 48:25 49:2 50:17 <b>tailored</b> 22:2 <b>take</b> 8:11 15:1,25 60:11 62:24 64:7 67:6 72:10 79:13 92:6 <b>telling</b> 54:17 88:4,8 89:17	<b>tells</b> 94:10 <b>ten</b> 82:25 <b>tension</b> 8:16 <b>teresa</b> 3:3 <b>term</b> 47:12 82:12 82:14,14,14,15,17 82:18,25 <b>terms</b> 38:22 41:17 77:22 <b>test</b> 25:19 <b>testified</b> 10:6 29:7 48:5 76:20 <b>testimony</b> 22:10 27:22 30:1,8 35:19 58:21,23 59:21 96:10,18 98:6,12 <b>thaman</b> 6:7 <b>thank</b> 27:17 <b>thats</b> 14:20 15:20 16:25 17:8 18:5 26:8 27:8,14 30:5 32:22 37:13 40:12 42:13 43:3,24 46:22 47:15 48:10 49:10 55:4 56:23 59:16 60:13,24 64:11,17 66:15 69:23 70:15 75:1 75:8,12,19 76:6 80:4,15 81:2 83:1 83:8 85:14 86:9 87:19 88:1 93:10 93:16 95:22,23 96:9 <b>theres</b> 12:16 22:3 31:9 37:5 40:19 41:18,23,24 43:16 45:10 50:6 73:15 76:14,25 78:15 90:6 93:13 96:17 <b>theyre</b> 21:4 35:24 41:7 47:7 56:16 <b>thing</b> 32:10 62:9 85:20 <b>things</b> 23:7 53:1
---	---	--	---	--

66:20 67:20	85:15	91:5	75:15	<b>vague</b> 26:19 87:2 92:15
<b>think</b> 12:24 13:3	<b>told</b> 39:3,4 87:23	<b>turnaround</b> 15:22	<b>understood</b> 35:19	<b>variety</b> 41:3 69:16
16:2,5 21:3,4,25	90:3 93:3	<b>turned</b> 16:3	<b>undertaken</b> 73:18	<b>various</b> 13:11,12 33:11 73:17 83:16
22:1,3 23:3,9,9	<b>top</b> 44:7 55:15	<b>turning</b> 81:17	<b>unfortunately</b> 42:7	94:20
26:10 38:11 46:19	68:14,18 90:7	<b>tv</b> 30:25 39:7,7,8,8	<b>united</b> 1:1 29:15 68:25	<b>verified</b> 38:7
48:5,6 51:21 55:2	<b>total</b> 40:19 42:14	39:8 43:6 44:1	<b>university</b> 11:14	<b>verify</b> 41:7
55:4 60:20 62:20	49:3	46:7,11 48:9,10	<b>unload</b> 86:13	<b>version</b> 54:19 74:8 74:8 86:6
68:16 74:20 76:18	<b>totaled</b> 60:17,22	48:11 49:8 50:5	<b>upcoming</b> 14:13	<b>versus</b> 94:11
77:1 78:24 79:13	<b>totaling</b> 60:24	51:13,17 59:25	<b>update</b> 12:6 50:24 52:21,25 55:8	<b>virginia</b> 1:2
82:10,23 83:10	<b>totality</b> 76:9	60:8,18,23 87:21	73:7	<b>virtue</b> 64:15 70:1
84:18 87:22 92:25	<b>totals</b> 45:24	94:7	<b>updated</b> 46:17	<b>vitro</b> 74:11
94:6	<b>track</b> 30:19	<b>tv</b> 39:7 51:18	53:25 54:19 55:4	<b>voluntary</b> 37:10
<b>thinking</b> 12:20	<b>tract</b> 50:2,20	<b>twelve</b> 22:14	55:8,25 59:3 88:1	<b>vs</b> 9:5 97:2 99:2
13:21 63:9	<b>training</b> 70:3	<b>two</b> 12:20,22,25	<b>updates</b> 25:15	<hr/> <b>W</b>
<b>third</b> 89:10	<b>transcribed</b> 98:8	13:4 15:16 24:21	73:13	<b>wagstaff</b> 7:12
<b>thirteen</b> 22:14	<b>transcript</b> 22:16	30:22 31:2 48:6	<b>updating</b> 26:4	<b>waiting</b> 14:17
<b>thomas</b> 6:9	23:15 98:11	67:19	<b>urinary</b> 50:2,20	<b>waive</b> 21:20
<b>thought</b> 23:23	100:20,22	<b>twothirds</b> 68:1	<b>urology</b> 8:15	<b>waived</b> 98:14
25:16,24 26:2	<b>transcription</b> 99:5	<b>twoyear</b> 83:8	<b>use</b> 9:11 13:7 14:1	<b>want</b> 15:14 16:2,9
56:4 57:23	<b>transfer</b> 37:9	<b>tyler</b> 6:12	14:3 38:22 47:12	16:15 43:15 53:19
<b>three</b> 16:21 23:8	<b>transferred</b> 37:1	<b>type</b> 41:16 42:5	70:7 75:5 86:4	55:8 62:9 64:7,9
38:14 82:14,17	<b>transvaginal</b> 15:7	45:11 51:2 95:13	88:24 89:4,9 90:8	65:13 67:25 70:21
<b>thurston</b> 6:11	51:7	<b>typed</b> 59:11	90:12,16,21 91:2	70:21 72:9 77:15
<b>time</b> 11:2 15:16,20	<b>treat</b> 24:16	<b>types</b> 29:24 48:15	92:8,11,14 93:2	81:5 82:11,21
26:19 27:2 32:6	<b>treatment</b> 81:2	49:25 50:7	93:21	85:20 87:13,14
32:21 33:15 34:20	<b>treatments</b> 82:7	<b>typical</b> 88:14	<b>user</b> 31:13	<b>wanted</b> 29:21 53:18
35:6,9,16 42:20	<b>tremendous</b> 12:17	<b>typically</b> 13:24	<b>users</b> 70:4	53:24 54:7 88:1
56:20 57:25 60:17	<b>trial</b> 23:12 27:1	45:9 93:19	<b>usually</b> 14:7	<b>warehouse</b> 61:14
61:17 75:22 78:25	58:24 75:17 77:16	<hr/> <b>U</b>	<b>utilize</b> 13:25	<b>warlick</b> 6:14
81:24 83:9,12,18	77:18 78:7,17	<b>u</b> 1:6 29:2,2,18 83:3	<hr/> <b>V</b>	<b>warn</b> 89:23 90:2
85:10 88:8 96:23	79:14 80:2,16,18	83:4	<b>v</b> 1:9,10,12,13,15	94:11
98:4,5,7	81:11 83:22 84:18	<b>ultimately</b> 25:13	1:17,19,21,23 2:1	<b>warnings</b> 90:13,23
<b>times</b> 33:15 49:12	84:24 85:4	<b>unable</b> 36:23 95:14	2:3,5,7,8,10,13,14	96:20
<b>title</b> 79:22	<b>trials</b> 11:10 55:16	<b>underneath</b> 62:11	2:16,18,20,22,24	<b>wasnt</b> 59:6,12
<b>titl</b> 8:18 32:14	56:23 57:2,6,20	85:22	3:1,3,5,7,9,11,13	<b>wave</b> 1:7 58:8
<b>today</b> 12:19 14:24	77:5 78:3 79:3	<b>understand</b> 18:18	3:15,17,19,21,23	<b>way</b> 17:23 26:24
19:3 23:1 26:2	<b>tried</b> 72:13	19:4,4 24:1,9	4:1,3,5,7,9,11,13	30:12 57:6 58:13
33:14 34:3,15,23	<b>trolling</b> 34:8	26:22 27:22 33:2	4:15,17,19,21,23	62:19 68:1 69:25
36:1,5,9,15,18	<b>true</b> 97:7 98:10,21	35:5 38:13 61:24	5:1,3,5,7,9,11,13	94:4
39:22 41:12 43:19	100:20,22	66:18,22,24 79:6	5:15,17,19,21,23	<b>ways</b> 15:16 91:25
43:23 46:5,16	<b>try</b> 43:10,11,23	87:4 89:22 91:25	6:1,3,5,7,9,11,12	<b>wcllp</b> 7:15
47:19 51:8 56:20	66:17 67:19 78:25	<b>understanding</b>	6:14,16,18,20,22	<b>website</b> 37:18,23
57:14 58:1,3,4	66:17 67:19 78:25	28:8,9,22 29:6	<b>vaginal</b> 8:17	
60:16,25 61:9	67:7 72:24 87:22	32:22 37:13 61:10		
63:14,24 64:8,10	67:7 72:24 87:22	66:4,25 67:13		
66:13 82:4 85:8	<b>turn</b> 66:15 85:17			

Peggy Pence, Ph.D.

Page 115

37:24 38:3,6 <b>wednesday</b> 7:4 10:1 <b>week</b> 58:16,18 <b>weeks</b> 12:17 14:18 51:22 60:17 <b>weighed</b> 70:8 <b>weisberg</b> 23:18 96:6 <b>weisbergs</b> 22:10 23:14 24:2 25:6 <b>went</b> 38:7 61:4,5,14 <b>west</b> 1:2 <b>weve</b> 84:14 <b>whats</b> 38:8 53:1 75:8 82:12 89:5 <b>white</b> 8:23 16:18 18:14 <b>williams</b> 6:16 <b>wilma</b> 4:1 <b>wiltgen</b> 6:18 <b>wishes</b> 65:8 <b>witness</b> 8:2 10:5 16:4,25 17:13 49:20 53:21 77:8 78:20 92:17 94:14 98:5,6 99:2 <b>wolfe</b> 6:20 <b>women</b> 84:6,8,17 <b>womens</b> 8:15 <b>wondering</b> 81:23 <b>wont</b> 49:18 61:10 <b>words</b> 13:25 <b>work</b> 10:25 15:21 37:9 45:20 60:2,5 60:10 65:8 <b>worked</b> 36:3 39:24 51:9 <b>working</b> 11:1,12 14:16 29:14,18 34:23 35:6,9,10 35:16,21 52:24 83:13 <b>works</b> 82:9 83:1 <b>worktable</b> 61:15 <b>worlds</b> 65:7	<b>worries</b> 31:19 56:3 <b>wouldnt</b> 29:16 47:5 52:13 <b>wrap</b> 94:5,8 <b>write</b> 17:8 84:9 <b>written</b> 59:7 62:24 69:15 71:16 79:16 <b>wrong</b> 61:5,14 <b>wrote</b> 28:1,5,7 86:6	45:5,5,21 60:14 <b>083</b> 40:19 <hr/> <b>1</b> <b>1</b> 1:7 8:11,18 14:20 14:21 19:17,18,24 20:2,4 22:8,17 23:16 24:5 31:24 32:1,14 54:21 58:8 69:17,19 81:19,21 90:5 99:4 <b>10</b> 8:4 9:7 70:15,16 71:7 72:1 73:7 88:21 89:1 <b>100</b> 7:5 60:23 <b>1020</b> 7:18 <b>11</b> 9:9 20:3 32:13 32:20 72:12,15,18 73:4,22 96:23 <b>1124</b> 7:14 <b>12</b> 7:5 9:10 10:2 12:17 86:15,16,19 <b>125666</b> 97:4 99:3 <b>12585</b> 7:4 98:1,25 <b>yellow</b> 17:10 <b>yeses</b> 78:24 <b>youd</b> 48:6 <b>youll</b> 26:23 28:1 61:21 73:4,9,21 88:14 89:2 <b>youre</b> 14:13 18:2 22:7 29:7 30:3 43:3 45:4 60:22 61:1,8,11 62:11 62:25 63:20,25 65:14 67:23 71:5 71:23 74:21 75:16 77:17 80:15,17,19 81:2,4,16 82:16 86:24 87:11 89:17 94:9 <hr/> <b>Z</b> <hr/> <b>0</b> <b>000</b> 40:21 44:12,16	<b>12cv00505</b> 6:11 <b>12cv00510</b> 4:24 <b>12cv00511</b> 6:17 <hr/> <b>12cv00516</b> 2:9 <b>12cv00517</b> 4:14 <b>12cv00554</b> 1:24 <b>12cv00567</b> 5:6 <b>12cv00595</b> 3:18 <b>12cv00651</b> 1:18 <b>12cv00654</b> 5:18 <b>12cv00663</b> 5:14 <b>12cv00666</b> 4:18 <b>12cv00683</b> 3:8 <b>12cv00746</b> 4:8 <b>12cv00747</b> 2:15 <b>12cv00748</b> 1:22 <b>12cv00779</b> 4:22 <b>12cv00786</b> 6:4 <b>12cv00806</b> 3:22 <b>12cv00809</b> 4:2 <b>12cv00829</b> 3:4 <b>12cv00848</b> 2:17 <b>12cv00861</b> 5:24 <hr/> <b>2</b> <b>12cv00878</b> 2:21 <b>12cv00887</b> 4:6 <b>12cv00931</b> 2:6 <b>12cv00938</b> 4:10 <b>12cv00957</b> 3:2 <b>12cv00960</b> 1:9 <b>12cv00997</b> 6:2 <b>12cv01011</b> 3:16 <b>12cv01013</b> 4:12 <b>12cv01021</b> 5:16 <b>12cv01023</b> 1:20 <b>12cv00443</b> 4:4 <b>12cv00455</b> 3:10 <b>12cv00469</b> 6:13 <b>12cv00470</b> 5:4 <b>12cv00476</b> 1:12 <b>12cv00481</b> 5:8 <b>12cv00483</b> 2:2 <b>12cv00486</b> 2:19 <b>12cv00493</b> 3:24 <b>12cv00499</b> 6:10 <b>12cv00500</b> 6:6 <b>12cv00501</b> 5:20
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Peggy Pence, Ph.D.

Page 116

<b>2003</b> 44:22 80:11	<b>3</b>	<b>67</b> 60:14	
<b>2005</b> 69:7 73:8,12 74:2,8 86:7,23 87:15 88:3 89:15	<b>3</b> 8:14 21:7,8 44:12 45:5 53:17 69:19 85:19,21 86:11	<b>7</b> <b>7</b> 8:22 18:4,8 88:24	
<b>2006</b> 37:6	87:12 99:5	<b>70</b> 9:7	
<b>2007</b> 44:23,23 72:8 72:10,11 73:10	<b>30</b> 23:12 49:11 <b>300</b> 7:13	<b>701</b> 7:14	
<b>2008</b> 50:24 56:15 57:25	<b>32</b> 66:16 <b>33</b> 69:8 70:20,25 71:17 74:13,22	<b>72</b> 9:9	
<b>2009</b> 83:17	<b>34</b> 60:14	<b>8</b> 8:23 18:13,15 20:3 37:22 79:21	
<b>2010</b> 49:9 79:24 83:17	<b>35</b> 91:5 <b>36</b> 91:5	89:5,11	
<b>2011</b> 34:24 35:8,10 35:16,17 44:9 50:25 51:5 86:23 87:15 88:3	<b>391586010</b> 7:19 <b>3rd</b> 21:17 24:25 31:7	<b>816</b> 7:14 <b>86</b> 9:10	
<b>2012</b> 25:12 26:7 29:9,11 30:2,10 37:15 44:12 45:4 56:15 57:25 73:7 74:8	<b>4</b> <b>4</b> 8:16 32:13 51:14 85:19 <b>40</b> 69:2,4	<b>9</b> 1:14 7:4,5 9:5 10:1,2 27:10,11 27:16,22 28:20 97:3 99:3	
<b>2013</b> 44:15 45:5 54:21,22	<b>41</b> 20:2 85:19 <b>42</b> 85:19	<b>92661</b> 10:16 16:11 <b>96</b> 8:5	
<b>2014</b> 26:10 28:5 29:9,11 30:2,10 55:2 56:20 57:19	<b>45</b> 96:23 <b>4523</b> 7:19 <b>4740</b> 7:13	<b>985</b> 7:19 <b>99</b> 46:7	
<b>2015</b> 22:10,15 27:3 28:21 39:5 46:7 46:14,15,17,18 55:2	<b>5</b> <b>5</b> 8:18 16:18,23 17:3 55:12,20		
<b>2016</b> 1:14 7:4 8:18 8:19 10:1 20:24 21:17 22:8,17,24 23:16 24:5,10,25 26:13 28:17 31:7 31:16,21 46:18 51:18,19 60:12 97:3 98:23 99:3	57:8 79:23 80:10 90:6 <b>50</b> 80:13 <b>500</b> 59:20 <b>51</b> 8:16 <b>516</b> 11:11 <b>54</b> 63:4 <b>5600</b> 7:5 <b>5th</b> 11:6		
<b>20year</b> 32:21 37:2			
<b>21</b> 8:14 63:4			
<b>23</b> 40:19,21	<b>6</b>		
<b>2327</b> 1:5	<b>6</b> 8:20 17:5,10,17 73:4 90:7		
<b>24th</b> 94:6	<b>60</b> 60:23		
<b>26</b> 8:12	<b>601</b> 7:19		
<b>27</b> 9:5	<b>64112</b> 7:14		
<b>270</b> 44:9			